COMPLAINT FOR DECLARATORY & EQUITABLE RELIEF CASE NO. 21-9640

Plaintiffs Center for Food Safety and Pesticide Action Network North America (Plaintiffs) on behalf of themselves and their members, allege as follows:

#### INTRODUCTION

- 1. This is an action for declaratory and equitable relief challenging the failure of the United States Environmental Protection Agency (EPA or the agency) to answer Plaintiffs' 2017 legal rulemaking petition, which the agency is required to do by law. The 2017 petition called on EPA to close a regulatory loophole that allows seeds coated with systemic pesticides (coated seeds) to evade the registration and labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's failure to respond to the petition and close the loophole means these pesticides are continuing to cause environmental harm unabated.
- 2. Coated seeds are crop seeds that have been coated with systemic pesticides, primarily neonicotinoid insecticides. Insecticides are a subcategory of pesticides. Neonicotinoids and other systemic pesticides are absorbed into the plant's circulatory system as the plant grows and are predominately intended to have an external pesticidal effect on pests and predators of the growing plant. Crops grown from coated seeds—including corn, soybean, and sunflower—cover almost 180 million acres of U.S. farmland each year. This is the equivalent acreage of over one-and one-half Californias.
- 3. Coated seeds have devastating environmental impacts. First, the pesticidal coating does not remain on the seed. The prophylactic pesticide coatings abrade off the seed as dust during planting, or slough off the seed into the surrounding soil. Overall, only 5% of the prophylactic coating is taken up by the plant, leaving 95% to contaminate the air, soil, vegetation, and waterways. Second, beyond coating the seed itself, these systemic pesticides spread through all living tissues of the growing plant, protecting the plant from pests but also spreading the poisonous effects to non-target species. As a result of both these pathways, beneficial insects, valuable pollinators, and birds—including threatened and endangered insects and birds protected under the Endangered Species Act (ESA)—are killed or injured. The most dramatic impacts of

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<sup>&</sup>lt;sup>1</sup> R. Sur & A. Stork, Uptake, Translocation and Metabolism of Imidacloprid in Plants, 56 Bulletin of Insectology 35-40 (2003).

- 4. Currently EPA entirely exempts coated seeds from FIFRA's pesticide's premarket licensing, registration, assessment, and labeling regime. Instead the agency has a de facto practice of applying the "Treated Article" Exemption in its regulations, 40 C.F.R. §152.25(a), despite the plain language of the Treated Article Exemption foreclosing the possibility that coated seeds are treated articles. Because the coated seeds are not treated primarily to protect the seed itself, but rather to protect the *growing plant*, they cannot be properly exempted as "treated articles" under the regulation. As a result, EPA has completely failed to assess the risks of these unregulated pesticides. It has also never provided the public with any justification for its exemption or codified that practice in its regulations.
- 5. On January 6, 2016, CFS filed a case challenging EPA's position that coated seeds are exempt from the requirements of FIFRA, as stated in the agency's 2013 Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents. EPA moved to dismiss the case on grounds that its 2013 guidance was not final agency action and thus not justiciable. The court denied EPA's motion. However at the summary judgment stage after review of the full administrative record the court held the 2013 guidance was not final agency action and therefore unreviewable.
- 6. In summary, the Court granted summary judgment to EPA because the agency had never actually publicly and formally admitted its Treated Seeds policy for exempting coated seeds. Instead the agency has for decades intentionally evaded any judicial review by failing to issue any final agency action on the topic.

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<sup>&</sup>lt;sup>2</sup> Anderson v. McCarthy, No. C 16-00068 WHA, 2016 WL 2770544, at \*3 (N.D. Cal. May 13, 2016).

<sup>&</sup>lt;sup>3</sup> Anderson v. McCarthy, No. C 16-00068 WHA, 2016 WL 6834215, at \*4 (N.D. Cal. Nov. 21, 2016).

1	7. Accordingly, on April 26, 2017, CFS filed a formal rulemaking petition. The
2	petition was a comprehensive 43-page scientific and legal document detailing the numerous
3	environmental impacts that the broad use of coated seeds causes, outlining EPA's authority under
4	FIFRA, and explaining why EPA's position is incorrect. The petition was supported by 81 citations
5	and supporting documents filed concurrently. Thus the petition provided both a legal blueprint
6	and legal impetus for EPA to either (1) amend the Treated Article exemption to clarify that it does
7	not apply to seeds coated with systemic pesticides, or (2) in the alternative publish a final, formal,
8	agency interpretation in the Federal Register stating that EPA interprets the Treated Article
9	Exemption not to apply to coated seeds. CFS further requested that EPA enforce FIFRA's
10	numerous pesticide registration and labeling requirements for each separate crop seed product that
11	is coated with a neonicotinoid or other systemic pesticidal chemical. CFS urged the agency to grant
12	the requests within 180 days of filing. Eleven organizations and beekeepers endorsed the petition,
13	including American Beekeeping Federation, American Bird Conservancy, American Honey
14	Producer's Association, Pollinator Stewardship Council, Bret Adee, Jeff Anderson, Lucas Criswell,
15	Gail Fuller, and David Hackenberg. The petition is attached as Exhibit A.
16	8. In December 2018, EPA opened a public notice and comment period in response
17	to the petition. 4 Many commenters were concerned that EPA's hands-off approach to coated seed
18	regulation has a devastating impact on bees and other pollinators. <sup>5</sup> Commenters agreed that the
19	Treated Article Exemption should not apply to coated seeds because that interpretation is contrary
20	to the purposes and intent of FIFRA,6 and that EPA is "improperly using the treated article
21	exemption as a way to abdicate itself of its duties under FIFRA."
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<sup>7</sup> *Id.* at EPA-HQ-OPP-2018-0805-0069.

<sup>&</sup>lt;sup>4</sup> EPA, Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration; Request for Comment, 83 Fed. Reg. 66260 (Dec. 26, 2018).

<sup>&</sup>lt;sup>5</sup> EPA, Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration, Docket No. EPA-HQ-OPP-2018-0805-0009, 0013, 0015, 0024, 0040, 0083 (Dec. 2018).

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 $<sup>^{6}</sup>$  Id. at EPA-HQ-OPP-2018-0805-0083.

<sup>28</sup> 

1	9. EPA's failure violates the mandates of the Administrative Procedure Act (APA),		
2	because EPA cannot unlawfully withhold or unreasonably delay a petition response. 5 U.S.C.		
3	§ 706(1). Nearly five years after Plaintiffs first lodged the 2017 Petition, EPA has still failed to		
4	respond. Irreparable environmental harm has continued unanalyzed and unabated in the interim.		
5	Plaintiffs' interests are continuing to be harmed by EPA's inaction and lack of oversight regarding		
6	coated seeds.		
7	10. Accordingly, this Court should hold that EPA's failure to act in response to the		
8	petition violates the APA and order EPA to respond to Plaintiffs' 2017 Petition by a Court-ordered		
9	date certain and without further unlawful delay.		
10	JURISDICTION		
11	11. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal		
12	question) and 1346 (United States as Defendant).		
13	12. Plaintiffs have a right to bring this action pursuant to the APA. 5 U.S.C.		
14	§§ 551-559, 702-706.		
15	13. The relief requested is specifically authorized pursuant to 28 U.S.C. §§ 1651 (writs)		
16	and §§ 2201 to 2202 (declaratory relief), as well as under the APA, 5 U.S.C. §§ 701-706. An actual		
17	controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory		
18	judgments).		
19	VENUE		
20	14. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or		
21	more Plaintiffs reside in this District.		
22	PARTIES		
23	Plaintiffs		
24	15. Plaintiffs Center for Food Safety (CFS) is a nationwide nonprofit organization with		
25	offices in San Francisco, California, Portland, Oregon, and Washington, DC. Founded in 1997,		
26	CFS's mission is to empower people, support farmers, and protect the earth from the harmful		
27	impacts of industrial agriculture. CFS has over a million members, including members in every		
28	state across the country, including many thousands of conservationists, gardeners, farmers, and		

beekeepers. CFS and its members are being, and will be, adversely affected by EPA's continued failure to answer CFS's legal petition and address the risks from coated seeds.

- 16. CFS combines myriad tools and strategies in pursuing its goals, including public education, grassroots organizing and campaigns, media, outreach, and when necessary public interest litigation and/or legal rulemaking petitions. CFS's membership action alerts also generate public education and engagement with governmental officials on issues related to addressing the health and environmental impacts of industrial agriculture, and promoting a healthier, more sustainable food system. Collectively, the dissemination of this material makes CFS an information clearinghouse for public involvement and governmental oversight of all aspects of industrial agriculture, including pesticides.
- 17. Since its inception twenty-five years ago CFS has had a flagship program on pesticides and pollinators, with multiple staff—science, policy, campaign, and legal. CFS's pesticide program has long advocated for rigorous, science-based safety testing and proper regulation of new pesticide product uses prior to any use, in a manner that minimizes negative impacts such as the increased use of pesticides and mortality to non-target species and addresses loopholes like the one at issue here. This specifically has included the issue of neonicotinoids and coated seeds. CFS has commented on numerous agency actions for pesticides, submitted petitions to agencies, and litigated various cases to prevent environmental harm.
- 18. Plaintiff Pesticide Action Network of North America (PANNA) is a Berkeley, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. It brings this action on behalf of itself and its members, particularly small-scale farmers, beekeepers, farmworkers, and indigenous members. For nearly thirty years, PANNA has worked to replace the use of hazardous pesticides with healthier, ecologically sound pest management across the United States and around the world. PANNA provides scientific expertise, public education and access to pesticide data and analysis, and policy development and coalition support to more than 100 affiliated organizations in North America. PANNA has more than 50,000 members across the United States. PANNA's members live, work, farm, and recreate in areas of the country

where pesticides such as the neonicotinoid insecticides are applied, and in which the pesticides
and contaminated dust drift and transport occurs, and thus have a strong interest in ensuring that
EPA protect public health and the environment from this contamination. PANNA's members are
highly concerned by the effects of the unregulated neonicotinoid-coated seeds on honey bees,
bumble bees, butterflies, beneficial invertebrates, wild pollinators, water, aquatic invertebrates,
food chains, ecosystem sustainability generally, and ultimately on humans via food and water
consumption. The lack of enforceable labeling on these pesticidal seeds, and their prophylactic
overuse, violate bedrock principles PANNA seeks to protect as far as only using pesticides as a last
resort, and then only when they have strong and clear warnings and enforceable use directions.
PANNA has repeatedly called on EPA to eliminate the coated seeds' exemption from registration
as pesticides, including by joining the 2017 petition.

#### Defendants

- 19. Under FIFRA, Defendant EPA is charged with the pre-market assessment and registration of pesticides, including the systemic pesticides used on coated seeds.
- 20. Defendant Michael Regan is sued in his official capacity as Administrator of the EPA. As Administrator, Mr. Regan has ultimate responsibility for EPA's activities and policies.
  - 21. Mr. Regan and EPA are collectively referred to herein as EPA or the agency.

#### LEGAL AUTHORITY

#### I. ADMINISTRATIVE PROCEDURE ACT

- 22. Pursuant to the APA, agencies must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). A "rule" is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4).
- 23. The APA requires an agency to conclude a matter presented to it, such as a legal petition like the one at issue here, "within a reasonable time." *Id.* § 555(b). If an agency denies a petition in whole or in part, it must provide "[p]rompt notice" to the petitioner. *Id.* § 555(e).
- 24. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. "Agency

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action" is defined to include not just affirmative agency action but also the "failure to act," id. § 551(13), such as the failure to respond to a legal petition.

25. Under the APA, courts "shall compel agency action unlawfully withheld or unreasonably delayed," id. § 706(1), and "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," id. § 706(2)(A).

#### FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT II.

- 26. FIFRA controls the manufacture, sale, and use of a broad range of chemicals and biological pest controls. 7 U.S.C. §§ 136-136y. As Congress explained, FIFRA's primary purpose is to protect human health and the environment. Pub. L. No. 92-516, 86 Stat. 973 (1972).
- 27. Pursuant to FIFRA, every pesticide must undergo registration with EPA before distribution or sale. 7 U.S.C. § 136a(a). A "pesticide" is defined very broadly, to mean "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," id. § 136(u)(1); the term "pest" includes insects, bacteria, and other microorganisms, id. § 136(t).
- 28. EPA may not register a pesticide unless it first determines and supports with substantial evidence that the pesticide "will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 36a(c)(5)(C), (D).
- 29. A pesticide is considered unregistered under FIFRA if its claims differ substantially from the claims made for the registered pesticide, or if its composition differs from the composition of the registered pesticide. 7 U.S.C. § 136j(a)(1)(B), (C). A new registration is required for a pesticide containing an active ingredient that has not been previously registered. 40 C.F.R. § 152.403. A new registration is also required prior to a new use of an existing registered pesticide. Id.
- 30. With regard to exemptions from FIFRA, the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines

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27 28 either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. § 136w(b).

31. EPA's implementing regulation for such exemptions provides that treated articles or substances are not regulated. 40 C.F.R. § 152.25. A treated article or substance is one which is "treated with, or containing, a pesticide to protect the article or substance itself." Id. § 152.25(a). EPA regulations exemplify this as "paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation." Id.

#### STATEMENT OF FACTS

#### Neonicotinoid Pesticides

- 32. Neonicotinoids are a class of insecticide chemically similar to nicotine, which disrupt the central nervous system of insects resulting in paralysis and death. Lower-level exposure has sublethal effects on insects, which include reductions in growth and reproduction, weakened immunity to parasites and viral diseases, and impaired learning and foraging behavior. These pesticides are systemic: unlike contact pesticides, which remain on the surface of the treated plant or seed, systemic pesticides are taken up by the growing seedling and transported to all its tissues (leaves, flowers, roots and stems, and pollen and nectar).
- 33. Neonicotinoids are highly soluble in water and quite persistent in the environment. Thus, it is not surprising to find neonicotinoids transported away from the initial application area to pollute surface water and groundwater. For instance, a survey conducted by the U.S. Geological Survey from 2012 to 2014 found one or more neonicotinoids present in 63% of the streams that were tested in 24 states and Puerto Rico.8
- 34. Neonicotinoids are the most widely used class of insecticides in the world. Studies show they are extremely harmful to pollinators, and strongly implicated in bee declines worldwide.
  - 35. An authoritative 2014 global review of over 800 published studies conducted under

<sup>&</sup>lt;sup>8</sup> Michelle Hladik & Dana Kolpin, First National-scale Reconnaissance of Neonicotinoid Insecticides in Streams Across the USA, 13 Env't Chemistry 12-20 (2016), https://pubs.er.usgs.gov/publication/70156299.

the auspices of the International Union for the Conservation of Nature (IUCN) determined that neonicotinoids are dangerously overused and should be restricted. A 2021 update to this review finds still more evidence of harms, linking neonicotinoid exposure to declines in wild bee and butterfly populations, warning that neonicotinoids' extreme toxicity to aquatic invertebrates "eliminates entire populations from the affected areas," and thereby threatens entire ecosystems.

36. In 2018, the European Union (EU) banned the primary neonicotinoids from all outdoor use. The United Nations states that neonicotinoids are so hazardous that their use should be severely restricted. Several states in the United States have also restricted neonicotinoid usage to protect bees and other pollinators. At the federal level, EPA has acknowledged the dangers of neonicotinoids and regulates them under FIFRA.

#### Neonicotinoid-Coated Seeds

- 37. While neonicotinoids themselves are regulated by EPA under FIFRA, EPA does not currently regulate neonicotinoid-coated *seeds*. However systemic neonicotinoid-coated seeds plainly fit within FIFRA's broad definition of "pesticide": they are a "mixture of substances that are intended to prevent, destroy, repel or mitigate a pest," and thus they should require pesticide registration approval prior to any sale or use. 7 U.S.C. § 136(u)(1). Instead, EPA has a de facto policy of treating them as exempt from the requirements of FIFRA and not requiring any registration.
- 38. Coated seeds are coated with liquid formulations of neonicotinoid chemicals, essentially turning the seeds into pesticide delivery devices. After the seeds germinate, the chemical coating delivers the active ingredient of the pesticide into the tissues of plants, via the growing plants' circulatory system. The tissues are typically hundreds or even thousands of times larger in dimension and mass than the seed itself, and are fundamentally different from a biological standpoint. The pesticide coating protects the plant from some insects; the coatings do not, in the vast majority of their uses, protect the seed itself against any disease or other risk to the seed.

<sup>&</sup>lt;sup>9</sup> Dave Goulson et al., An Update of the Worldwide Integrated Assessment (WIA) on System Insecticides Part 2: Impacts on Organisms and Ecosystems, 28 Env't Sci. Pollution & Rsch. 11749-97 (2021).

- 39. Reviewing the many pesticide product labels that EPA has registered since 2010 reveals that in the vast majority of those labels the neonicotinoid ingredients are intended to protect the growing crop plants. Few of those labels explicitly claim protection of the planted seed itself by the neonicotinoid ingredient.
- 40. Crop seeds coated with neonicotinoid throughout the United States, include but are not limited to:
  - Canola
  - Field and sweet corn
  - Cotton
  - Cucurbits
  - Legume vegetables
  - Potatoes
  - Sovbean
  - Sunflowers
  - Wheat
- 41. These seeds are used on nearly 180 million acres across the United States, representing the vast majority of systemic insecticide use and covering close to one-fifteenth of the entire land surface of the lower forty-eight states.
- 42. Despite being used over such a large land area, neonicotinoid seed treatments provide little or no benefit. They are largely ineffective on corn's worst pest, corn rootworm, <sup>10</sup> and an EPA study showed that any benefits of neonicotinoid seed treatments to soybean farmers were "negligible." <sup>11</sup> Despite this, seed companies often give farmers little or no choice of uncoated seeds, particularly uncoated corn seed.
- 43. Planting coated seeds results in exposure of non-target organisms even in those frequent instances when pests are not present at damaging levels. Such prophylactic or "insurance-

<sup>&</sup>lt;sup>10</sup> Marlin Rice, Seed-Treatment Insecticides: What Can We Expect in Terms of Broad-Spectrum Control of Soil Insects? Proc. of Ind. Crop Advisory Conf. (2004).

<sup>&</sup>lt;sup>11</sup> U.S. Environmental Protection Agency, Benefits of Neonicotinoid Seed Treatments to Soybean Production (Oct. 15, 2014).

based" use of pesticides is contrary to Integrated Pest Management (IPM), which strives to eliminate senseless pesticide applications. 12

#### Environmental Effects

- 44. Neonicotinoids associated with coated seeds are found widely throughout the environment, and the agricultural landscape is up to 48 times more toxic to insects than it was 25 years ago.<sup>13</sup>
- 45. Since neonicotinoids are systemic, they are found in the crops grown from treated seeds including the leaves, pollen, and nectar. Neonicotinoids disrupt the central nervous system of insects, and do not discriminate between target and non-target insects, so affect insects and pollinators such as bees that consume the nectar or pollen of the treated crop.
- 46. On average only 5% of the neonicotinoid coating is absorbed by the crop, leaving roughly 95% of the active ingredient to diffuse into the surrounding soil and soil water, and eventually into waterways. In addition, neonicotinoid coatings are abraded off into the talc or other lubricant added to seed boxes to prevent coated seeds from sticking together, and the neonicotinoid-rich lubricant dust lost during planting travels long distances on the wind during planting. In short, the bulk of the coating does not remain in or on the treated articles: the seeds. The result is widespread contamination of the air, soil, marginal vegetation, waters, neighboring farms, and beehives. Pesticide contamination thus results on vast areas extending far beyond the planted fields, affecting non-target organisms.
- 47. Neonicotinoids persist in the environment, creating the potential for increasing concentrations in the soil over time with repeated use, exacerbating risks to non-target organisms.
- 48. The effects on wildlife range from direct harm to both managed and wild bees and other beneficial terrestrial insects, to contaminated runoff decimating aquatic invertebrates, to

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Jacob Pecenka et al., IPM Reduces Insecticide Applications By 95% While Maintaining Or Enhancing
 Crop Yields Through Wild Pollinator Conservation. 118 Proc. Nat'l Acad. Sci. USA (2021).

<sup>&</sup>lt;sup>13</sup> Kendra Klein & Anna Lappé, America's agriculture is 48 times more toxic than 25 years ago. Blame neonics, The Guardian (Aug. 2019).

both acute and chronic effects on birds that ingest the coated seeds. Traces of residual neonicotinoids can have a mixture of lethal and sublethal effects on a wide range of taxa.

- 49. Many beekeepers have observed toxic dust clouds billowing from seed planting machines, spreading neonicotinoids into integral bee habitat. Honey bee kill incidents caused by coated seeds have numbered in the hundreds and the true number is likely far higher. These incidents have killed hundreds of millions of individual bees due to acute dust-off kills and chronic damage to bee hives. Sublethal doses can result in honey bee colony damage through chronic effects, which compromise the behavior and immunity of bees, and the health of entire colonies, contributing to substantial losses under the additional stress of pathogens and parasites.
- 50. Harm to noncommercial bees and other pollinators is equally deadly. Species such as bumblebees, ground-nesting mining bees, alkali bees, squash bees, and long-horned sunflower bees are devastated by repeated, persistent use of coated seeds. Adverse impacts to other species of native bees that are not ground nesters has also been identified through exposure routes such as contamination of nesting materials. The harm to pollinators harms U.S. agriculture, which relies on wild pollinators to pollinate food crops.
- 51. Because neonicotinoids are water soluble, increasing contamination of ditches, streams, groundwater, lakes, rivers, and marine areas is being documented, with coatings applied to crop seeds a primary source of the contamination. The three major neonicotinoids were found to be prevalent throughout the year in sampled tributaries to the Great Lakes, the largest freshwater ecosystem in the world. EPA has found ongoing chronic effects for many aquatic invertebrates and some groups likely to suffer acute effects. Aquatic invertebrates are core contributors to nutrient cycling, water quality, and aquatic food webs that support fish and wildlife, so lethal and sublethal effects to these organisms can have far-reaching consequences.

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- 52. Slugs that consume neonicotinoid-coated soybean seeds and seedlings take the insecticide into their tissues; while they are unaffected, beneficial predatory ground beetles that prey upon them are killed, resulting in higher slug populations that lower soybean yield.<sup>14</sup>
- 53. Bird species are being exposed to and harmed by coated seeds. Small to medium-sized birds are at risk of death from consuming just one to four small seeds of crops like sorghum or wheat, a credible risk given shallow planting and many birds' predilection for energy-rich seeds. Birds could also be harmed by eating neonicotinoid-intoxicated organisms like slugs or earthworms. In addition to direct mortality to birds from ingesting neonicotinoid-coated seeds, research has demonstrated sublethal effects, such as reduced body fat and disorientation.
- 54. Coated seeds have been documented as seriously harming humans and pet dogs despite neonicotinoids supposedly not affecting large mammals. In Nebraska, a bioethanol company fed surplus neonicotinoid coated corn seeds into its bioethanol plant, resulting in polluted water and soil to levels posing serious health threats to people and animals. Tests on the corn waste emanating from the plant revealed neonicotinoid levels as high as 427,000 parts per billion, emphasizing the need for proper regulation of coated seeds and strict enforcement. People reported eye and throat irritation and nosebleeds. Pet dogs grew ill, staggering about with dilated pupils, while colonies of bees died, and birds and butterflies were afflicted with neurological damage as well. Residents who reported the debacle to EPA said the agency's response was that it did not think it could do anything about the problem. <sup>15</sup>
- 55. Humans are increasingly getting exposed to neonicotinoids through the food supply and water contamination. Neonicotinoids have been found in fruits such as apples,

<sup>&</sup>lt;sup>14</sup> Margaret Douglas et al., Neonicotinoid Insecticides Travels Through A Soil Food Chain, Disrupting Biological Control Of Non-Target Pests And Decreasing Soya Bean Yield, 52 J. of Applied Ecology 250-260 (2014).

<sup>&</sup>lt;sup>15</sup> Carey Gillam, 'There's a red flag here': how an ethanol plant is dangerously polluting a US village, The Guardian (Jan. 10, 2021), https://www.theguardian.com/us-news/2021/jan/10/mead-nebraska-ethanol-plant-pollution-danger; Chris Dunker, Public records reveal frustration as state sought to deal with pesticide dangers from ethanol plant, Lincoln Journal Star (Nov. 21, 2021), https://journalstar.com/news/state-and-regional/nebraska/public-records-reveal-frustration-as-state-sought-to-deal-with-pesticide-dangers-from-ethanol-plant/article\_60cc64ea-0e7b-5081-8148-d453be8cce90.html.

cherries, and strawberries, as well as honey and baby food. Neonicotinoids are ubiquitous in surface waters and may be contaminating aquifers. Human urine samples show that at least half the U.S. population is exposed to neonicotinoids on a regular basis. Epidemiological studies have found suggestive evidence that neonicotinoid exposure may be linked to developmental or neurological effects including malformations of the developing heart and brain, autism spectrum disorder, and a cluster of symptoms including memory loss and finger tremors, though further research is called for. Coated seeds have facilitated the increased use and spread of neonicotinoids through the environment, heightening the risks to the environment, wildlife, and humans.

#### Harm to Endangered and Threatened Species

- 56. Pesticide escape into the environment associated with coated seeds affects a vast number of non-target species, including those protected under the ESA.
- 57. The Fish and Wildlife Service (FWS) found that neonicotinoid-coated seeds were strongly implicated as a factor endangering the Rusty Patched Bumble Bee. Pollinators such as the Rusty Patched Bumble Bee foraging on treated plants are exposed to the chemicals directly. Coated seed technology allowed neonicotinoids to become large-scale, preemptive pesticides, and that increased use is correlated with a precipitous decline of the species.
- 58. Two butterflies, the Dakota skipper (*Hesperia dacotae*) and Poweshiek skipperling (*Oarisma poweshiek*), listed under the ESA in 2014 also had neonicotinoid-coated seeds explicitly singled out by the FWS as a significant factor that led to their listings.
- 59. On August 26, 2021, EPA released draft ESA Biological Evaluations (BE) for neonicotinoids to evaluate their effects on species and their critical habitat. EPA's draft BEs showed widespread harm was predicted. For example, the agency expects nearly 80% of all endangered species—1,445 different kinds of plants and animals—are likely to be "adversely affected" by the neonicotinoid imidacloprid, and the pesticide will adversely modify the designated critical habitats of 658 species.
- 60. However, in the draft BEs EPA did not even conduct a quantitative risk assessment of ecological harm from neonicotinoid seed treatments, and moreover failed to even provide any

estimate of the total amount applied to seeds, despite the fact that seed treatments are by far the major use of these insecticides.

# The Treated Article Exemption

- 61. EPA first issued the Treated Article Exemption, 40 C.F.R. § 152.25(a), in 1988. Neonicotinoid-coated seeds were neither mentioned in the regulation text nor in the Federal Register notice accompanying the exemption, and were not in use in agriculture at the time.
- 62. By the early 2000, coated seeds were coming into use in agriculture. And in 2003, EPA and the Pest Management Regulatory Agency of Canada jointly issued a paper called *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* (Harmonization Paper). The Harmonization Paper concluded that coated seeds should be *excluded* from the Treated Article Exemption: "The term 'for the protection of the [seed] itself' means that the pesticidal protection imparted to the treated seed does not extend beyond the seed itself." The Harmonization Paper otherwise provided no coverage or analysis of systemic pesticides or neonicotinoid-coated seeds.
- 63. Despite this interpretation EPA has instead persisted in practice in its view that the Treated Article Exemption *does* include systemic coated seeds, despite the intended and actual pesticidal effects extending far beyond the articles (seeds) themselves. At the same time the agency has studiously avoided making this interpretation formal or final in any final agency action.
- 64. In practice EPA neither requires registration of the seeds nor imposes enforceable labeling on their bags or tags, labeling that would otherwise be required under FIFRA.
- 65. Not only does the extension of the Treated Article Exemption to these pesticidal seeds violate the exemption's plain language, it also violates the basic FIFRA safety standard. EPA cannot exempt a pesticide that violates this safety standard, *i.e.*, that the pesticides *as commonly used* will not cause unreasonable adverse effects to the environment.

Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States April 11, 2003, pp. 1-2, (Joint Regulatory Directive of EPA and the Pest Management Regulatory Agency of Canada), perma.cc/3MUH-B9VQ.

# Anderson et al. v. McCarthy17

- 66. On January 6, 2016, CFS filed a case challenging EPA's position that coated seeds are exempt from the requirements of FIFRA.
- 67. Specifically, Plaintiffs in that case sought review of a 2013 guidance document issued by EPA stating that coated seeds may be exempted from the requirements of FIFRA under the treated article exemption. Plaintiffs argued that the 2013 Guidance was a final agency action establishing the coated seeds exemption and as such exceeded EPA's statutory authority, failed to comply with the APA's rulemaking requirements, and was arbitrary and capricious. They also argued that EPA's "non-enforcement policy" for coated seeds was an unlawful abdication of the agency's duties under FIFRA.
- 68. The case was decided on procedural grounds. After first denying a motion to dismiss and ordering production of the administrative record, on cross motions for summary judgment the court concluded that while it was "most sympathetic to the plight of our bee population and beekeepers," there was not any EPA final agency action on the issue that could be challenged. <sup>18</sup>

#### Plaintiffs' 2017 Petition

- 69. EPA is tasked with regulating the use of pesticidal products in order to protect public health and the environment. Pub. L. No. 92-516, 86 Stat. 973. As part of that responsibility, EPA must ensure that pesticides are registered under FIFRA. Nevertheless, EPA continues to insist that coated seeds fall under the Treated Articles Exemption.
- 70. In addition to failing to comply with FIFRA by declining to require registration of coated seeds, EPA has so far also failed to comply with mandates in the ESA that require consideration of the adverse impacts of coated seeds on threatened and endangered species, 16 U.S.C. § 1536.

Complaint for Declaratory & Equitable Relief Case No. 21-9640

<sup>&</sup>lt;sup>17</sup> Anderson v. McCarthy, No. C 16-00068 WHA, 2016 WL 6834215 (N.D. Cal. Nov. 21, 2016).

<sup>&</sup>lt;sup>18</sup> *Id.* at \*13.

- 71. A few months after the court dismissed the first coated seeds case, on April 26, 2017, Plaintiffs submitted a legal petition for rulemaking to EPA urging the agency to remedy those failures, on behalf of itself and 10 other entities. Specifically, the petition requested, *inter alia*, that EPA take the following actions:
  - (1) Amend 40 C.F.R. § 152.25(a) to clarify that it does not apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself; or
  - (2) In the alternative publish a final, formal, agency interpretation in the Federal Register stating that EPA interprets the exemption in 40 C.F.R. § 152.25(a) not to apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself.
  - (3) Analyze the potential human health and environmental risks of coated seeds under the ESA; and
  - (4) Enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical.
- 72. On December 25, 2018, EPA opened a sixty-day public comment period in response to Plaintiffs' petition. Petition Seeking Rulemaking or a Formal Agency Interpretation for Planted Seeds Treated With Systemic Insecticides; Request for Comment, 83 Fed. Reg. 66,260 (Dec. 26, 2018). The comment period ran until March 26, 2019 and attracted 16,343 comments.
- 73. Public comments highlighted the agency's flawed basis for exempting coated seeds as treated articles, as well as the harm EPA's insufficient regulation of coated seeds has caused and is causing to pollinators, birds, aquatic organisms, and the environment.
- 74. In the approximately five years since Plaintiffs filed the petition, the agency still has not issued a response or answer to the petition in whole or in part.

# EPA's Ongoing Failure to Meaningfully Examine or Regulate Coated Seeds

75. Despite refusing to codify the loophole for coated seeds, EPA is very aware that neonicotinoids are used on coated seeds, and that they are creating lasting environmental damage. As long ago as 2003, EPA assessments showed that exposure to treated seeds posed toxic risks to

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birds and mammals. Since then, EPA has conducted risk assessments and studied the impacts of neonicotinoids on pollinators but has routinely ignored the contribution of coated seeds.

- 76. EPA requires labels to be placed onto the bags or other containers, or onto the affixed tags, of the unregistered pesticidal seeds, which include some sparse warnings superficially aimed at protecting pollinators and other environmental values. While these amount to admissions of the seeds' harmful pesticidal effects, the label language itself is unenforceable by EPA's own statements and its inactions.
- 77. Even were they enforceable, the bag labels are inadequate to protect against the vast spectrum of environmental and economic impacts, including, but not limited to, death of pollinators, damage to soil and aquatic life, lethal and sublethal effects on birds, and harm to ESAprotected species.
- 78. In its proposed interim registration review for the neonicotinoid imidacloprid, published in January 2020, EPA decided that this pesticide was too hazardous to be applied via onfarm seed treatment activities to canola, millet, and wheat, even when wearing the maximum possible protective clothing. EPA therefore added the statement "Must be applied in commercial seed treatment facilities only" to the label. 19 Yet despite acknowledging that seed treatment was the primary method for dispersing these hazardous chemicals, EPA did not fully analyze the environmental impacts of this use.
- 79. Perhaps most problematically, EPA has never provided the public with any justification for treating coated seeds as exempt from the registration and labeling requirements of FIFRA.

#### EPA's Failure to Respond to the 2017 Petition

80. Almost five years have passed since Plaintiffs filed its 2017 legal petition providing the legal blueprint and impetus for EPA to amend its regulations to make clear that coated seeds are not covered by the Treated Article Exemption and to enforce the requirements of FIFRA. Yet EPA still has not responded to that petition.

<sup>&</sup>lt;sup>19</sup> EPA, Imidacloprid Proposed Interim Registration Review Decision, Case Number 7605, at 41 (Jan. 2020).

81. The APA requires that agencies respond to petitions within a reasonable time and without undue delay. While the reasonableness of the time taken by the agency to respond varies depending on the circumstances, it does not usually extend to years like it has here and particularly not in these circumstances. Subsequent to the 2018 comment period, EPA has gone silent and has not indicated any timeline by which it will answer the 2017 Petition. Five years is an especially egregious delay in cases like this where the delay involves danger to the environment and/or public health. Pollinators, threatened and endangered species, American agriculture, human health, and the environment have all suffered because of EPA's failure to regulate. EPA acknowledges the risks of neonicotinoid pesticides and has cancelled the registration of several neonicotinoids in the past, but continually refuses to address the most common form in which neonicotinoids are used – as seed coatings. Because EPA has not yet acted on coated seeds, the environmental damage caused by coated seeds has likely compounded, endangering human health and hastening the insect apocalypse.

#### Harm to Plaintiffs

- 82. EPA's failure to respond to the petition injures Plaintiffs' informational and organizational interests, and injures Plaintiffs members' interests.
- 83. Plaintiffs have a right under the APA to a timely response to their rulemaking petition, and are injured by EPA's failure to provide it, in violation of the APA.
- 84. EPA's unlawful delay in responding to the 2017 Petition injures Plaintiffs by, *inter alia*, denying them important and urgently needed information about EPA's oversight of pesticidal coated seed products in the form of a petition response—a response to which the Plaintiffs is statutorily entitled under the APA. By denying Plaintiffs the vital and urgent information in a petition response, EPA's failure to respond to the 2017 Petition has violated Plaintiffs' procedural and substantive rights under the APA.
- 85. Additionally, EPA's failure to act on the petition directly harms Plaintiffs' concrete organizational interests by impeding their abilities as public interest nonprofit organizations to facilitate public involvement in governmental decision-making, and by foreclosing the statutory right that allows for public participation through petitions for rulemaking. As such, EPA's failure

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to act has effectively negated Plaintiffs' right to petition a federal agency for rulemaking under the APA.

- 86. Further, EPA's continued failure to respond to the 2017 Petition deprives Plaintiffs of a decision on the Petition's merits and, if necessary, the opportunity to seek judicial review of EPA's final decision.
- 87. Plaintiffs' members' concrete interests in their health and environmental protection, are being and will be adversely affected by EPA's continued failure to respond to the 2017 Petition. Specifically, Plaintiffs' members are suffering or will suffer an ongoing threat to their health, their children's health, and, for farmers and beekeepers, their livelihoods, as well as the health of the natural environment. Plaintiffs members' myriad interests in the natural environment and endangered species, honey and wild native bees, and other pollinators environmental, conservation, professional, recreational, and aesthetic interests—continue to be injured by EPA's failure to answer the petition and regulate coated seeds.
- 88. The requested relief will redress these harms by requiring EPA to respond to the Petition, resulting either in a response that fulfills EPA's statutory duties by protecting public health and the environment from the risks of coated seeds, and/or a final agency action that Plaintiffs may challenge in federal court if they disagree with the agency's response, in whole or in part. Both results would provide Plaintiffs organizations with APA-mandated information, securing their procedural right to receive a timely response to a legal petition for rulemaking and safeguarding their members' interests.

#### **CLAIM FOR RELIEF**

#### VIOLATION OF THE APA

- 89. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 88 supra.
- EPA is an "agency" under the APA. See 5 U.S.C. §§ 551(1), 701(b)(1). The APA 90. requires agencies to "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." Id. § 553(e); see id. § 551(4) (defining "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret,

or prescribe law or policy"). The APA right to petition encompasses the right to petition for a new, revised, or final rule concerning EPA oversight of pesticides and related substances such as coated seeds. See id. §§ 551, 553(e).

- 91. Upon receipt of an APA petition, EPA has a duty to provide a timely response to the petitioners. *Id.* § 555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person . . ."). Such response must be substantive—*i.e.*, it must either grant or deny the petition, in whole or in part.
- 92. EPA cannot "unlawfully withhold or unduly delay" the Petition response, *id*. § 706(1), which it has here, for nearly five years, with environmental harm ongoing unabated.
- 93. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. Agency action includes agencies' failure to act, as here. Plaintiffs and its members are adversely affected by EPA's past and continued failure to respond to the 2017 Petition.
- 94. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1). EPA's failure to respond to and act on the 2017 Petition constitutes unlawfully withheld and unreasonably delayed agency action.

#### RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

- (1) Declaring that EPA has violated the APA by failing to provide a timely response to the 2017 Petition;
- (2) Declaring that EPA continues to be in violation of the APA by failing to respond to the 2017 Petition;
- (3) Ordering EPA to respond to the 2017 Petition by a Court-ordered date certain, by no more than 90 days;
- (4) Retaining jurisdiction of this action to ensure compliance with this Court's decree;
- (5) Awarding Plaintiffs attorneys' fees and all other reasonable expenses incurred in pursuit of this action; and

(6) Granting other such relief as the Court deems just and proper. Respectfully submitted this 14th day of December, 2021, in San Francisco, California. /s/Sylvia Shih-Yau Wu SYLVIA SHIH-YAU WU (CA Bar No. 273549) GEORGE KIMBRELL (Pro Hac Vice pending) Center for Food Safety 303 Sacramento Street, 2<sup>nd</sup> Floor San Francisco, CA 94111 Phone: (415) 826-2770 Emails: swu@centerforfoodsafety.org gkimbrell@centerforfoodsafety.org Counsel for Plaintiffs 

# Exhibit A

# CITIZEN PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

	)
BRET ADEE, AMERICAN BEEKEEPING	, )
FEDERATION, AMERICAN BIRD	)
CONSERVANCY, AMERICAN HONEY	)
PRODUCERS ASSOCIATION,	)
JEFF ANDERSON, LUCAS CRISWELL,	)
GAIL FULLER, DAVID HACKENBERG,	) Docket Number
PESTICIDE ACTION NETWORK OF	
NORTH AMERICA and POLLINATOR	)
STEWARDSHIP COUNCIL	)
including and represented by	)
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,	)

### **EXECUTIVE SUMMARY**

This Citizen Petition seeks to end an existing regulatory loophole for seeds coated with systemic pesticides. The Environmental Protection Agency (EPA) is tasked with regulating pesticides in the United States, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 et seq. However, a class of pesticides made up of crop seeds coated with systemic insecticides ("coated seeds") that are intended to kill pests of the plants are not regulated by EPA under FIFRA. Although these seeds fit the definition of "pesticide" and have devastating impacts to the environment and Petitioners' interests, EPA exempts the coated seeds

from FIFRA's registration and labeling requirements, improperly relying on the Treated Article Exemption, 40 C.F.R. §152.25(a).

Petitioners are commercial beekeepers, farmers, and environmental and agriculture public interest groups, all with a keen interest in ending this loophole for these pesticide-coated seeds. These seeds are used on nearly 150 million acres across the country, representing the vast majority of systemic insecticide use, where they cause both acute and chronic bee kills, contribute to pollinator decline, pollute soil and water, and harm wildlife, including threatened and endangered invertebrate and bird species. Excessive honey bee mortality and wild pollinator declines are a major crisis for American agriculture as so many of our food crops require pollination. Because the coated crop seeds are not treated primarily to protect the seed itself, but rather to protect the growing plant, and have vast adverse impacts beyond the seed, they cannot be properly exempted as "treated articles." Nor can EPA continue to allow the coated seeds to avoid compliance with FIFRA's mandatory safety standards and enforceable labeling requirements.

This Petition seeks an amendment to, or a formal re-interpretation of, the Treated Article Exemption, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pesticidal seeds intended to kill insect pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements. Petitioners also request that EPA aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated with a systemic insecticide.

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# CITIZEN PETITION TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY SEEKING RULEMAKING OR A FORMAL AGENCY INTERPRETATION FOR PLANT SEEDS COATED WITH SYSTEMIC INSECTICIDES

#### INTRODUCTION

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 *et seq.*, the Environmental Protection Agency (EPA) regulates pesticide use in the United States. Currently, EPA does not enforce FIFRA's requirements as to a class of pesticides that includes crop seeds coated with systemic insecticides intended to kill pests of the plants. EPA improperly interprets the Treated Article Exemption, 40 C.F.R. §152.25(a), to exempt these pesticidal seeds from FIFRA's registration and labeling requirements. However, this class of pesticides causes widespread adverse effects on the environment and its exemption violates FIFRA for the reasons detailed herein. This Petition seeks an amendment to, or a formal re-interpretation of, that EPA regulation, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pestidical seeds intended to kill pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements for registration and labeling. To continue this unlawful exemption would be severely detrimental to Petitioners' interests. Petitioners also request that EPA aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated in systemic insecticides.

EPA has allowed millions of pounds of crop seeds, such as corn, soybean, and sunflower seeds, planted on almost 150 million acres each year, to be coated with four systemic insecticide active ingredients: acetamiprid, clothianidin, imidacloprid, and thiamethoxam (hereinafter "neonicotinoids"). These seeds coated with neonicotinoids and other systemic insecticides

<sup>&</sup>lt;sup>1</sup> Brassard, D. 2012. Memorandum - Estimated Incremental Increase in Clothianidin Usage from Pending Registrations. EPA Biological Analysis Branch, Biological and Economic Analysis Division, Office of Chemical Safety and Pollution Prevention; *See* Answer ¶ 2, *Anderson v. McCarthy*, No. 3:16-cv-00068-WHA, ECF No.67 (N.D. Cal. May 27, 2016) ("between 2010 and 2014, approximately 142 million acres on average were planted with

intended to protect the plant will be referred to throughout as "coated seeds." Approximately ninety-five percent of the land area in the United States that is treated with any neonicotinoid insecticide is treated via planting coated seeds.<sup>2</sup> In the vast majority of cases, the coatings are not intended to protect the seed itself from any disease, pest, or predator. Rather, the coating chemicals are *systemic*, meaning they are absorbed into the plant's circulatory system as the plant grows and are predominately intended to have an external pesticidal effect on pests and predators of the growing plant. That effect is exerted not only on plant pests, but also on beneficial insects, valuable pollinators, and birds, including threatened and endangered species protected under the Endangered Species Act (ESA).<sup>3</sup> For many coated crop seeds, the coatings are abraded off of the seed as dust or are sloughed off the seed into the surrounding soil. Indeed, more than eighty to ninety percent of the chemical coating can move off of the seed to contaminate the air, soil, marginal vegetation, and waters.<sup>4</sup>

Over the past decade the increasing use of seeds coated with neonicotinoid insecticides has coincided with mass die-offs of honey bees and wild native bees. If left unchecked, these losses could precipitate an economic and ecological disaster impacting the Petitioners and the United States as a whole at a time when the nation can ill afford it. Honey bees not only produce nutritious honey, but are also of enormous economic importance to American agriculture as pollinators. About ninety percent of all flowering plants require pollinators to reproduce and nearly a third of pollination is performed by bees in American agriculture. 5 Honey bee

seeds treated with [neonicotinoid] pesticides."). Note: after the initial filing of this Petition, copies of the footnoted supporting documents will be subsequently provided or their location will be indicated to EPA.

<sup>&</sup>lt;sup>2</sup> Thomas Steeger, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA. *Bee health in the USA and the debate about Neonicotinoids*. Powerpoint dated April 11, 2014. Slide 8.

<sup>&</sup>lt;sup>3</sup> 16 U.S.C. 1531 et seq.

<sup>&</sup>lt;sup>4</sup> Goulson, D., 2014. Pesticides linked to bird declines. *Nature* 511:295-296; doi:10.1038/nature13642.

<sup>&</sup>lt;sup>5</sup> United Nations, Food and Agriculture Organization. *Global Action on Pollination Services for Sustainable Agriculture*. Undated background report, *at* http://www.fao.org/pollination/background/en/; Johnson, R. and Corn,

pollination adds tens of billions of dollars annually in crop value. Healthy populations of all pollinators are essential for the future of American agriculture.

EPA has allowed this threat to pollinators to transpire without requiring the seeds to be registered under FIFRA or for the seed bags or tags to bear mandatory or enforceable labeling under FIFRA. The Agency has failed to adequately assess the risks of the unregulated seeds, instead exempting them from registration or labeling requirements and only registering the liquid coating products. EPA has never provided the public with any justification for its exemption. EPA's actions and inactions have led to excess bee colony mortality, declines in native bees, increased bird mortality, nationwide soil and water contamination, contaminated marginal vegetation and other environmental and economic harms, thereby severely damaging the Beekeeper Petitioners' businesses, while also damaging the land and welfare of the Farmer Petitioners and damaging the interests of the Public Interest Organization Petitioners.

EPA has approved other non-neonicotinoid systemic insecticides and appears poised to register additional systemic seed coatings. If additional systemic seed coatings are registered, the resulting seeds will present the same potential damage to Petitioners as the unregulated and unlabeled neonicotinoid-coated seeds. Thus, they also are subject to Petitioners' requests herein.

#### **PETITION REQUESTS**

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution<sup>6</sup> and the Administrative Procedure Act (APA),<sup>7</sup> Petitioners

L. 2015 Bee Health: Background and Issues for Congress. Congressional Research Service, No. 7-5700, at https://fas.org/sgp/crs/misc/R43191.pdf.

<sup>&</sup>lt;sup>6</sup> U.S. CONST. amend. I.

<sup>&</sup>lt;sup>7</sup> 5 U.S.C. § 553(e).

request the Administrator of EPA to take the following actions (please note Requests No. 1 and 2 are in the alternative):<sup>8</sup>

1. Amend 40 C.F.R. § 152.25(a) to clarify that it does not apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself (shown in red):

Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation, but excluding seeds for planting coated with a systemic pesticide intended to kill pests of the plant) if the pesticide is registered for such use.

- 2. Alternatively, publish a final, formal, agency interpretation in the Federal Register stating that EPA interprets the exemption in 40 C.F.R. § 152.25(a) not to apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself.
- 3. Aggressively enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical.

Failure by the Administrator to take the requested actions would severely harm Petitioners' interests. It also would violate the mandates of FIFRA and would be arbitrary and capricious. In view of the severity of the impacts the Petitioners are suffering and EPA's excessive delays in resolving the concerns over its past application of the Treated Article

<sup>&</sup>lt;sup>8</sup> EPA's lacks regulations for handling public petitions related to pesticides, a problem it has been urged by its Inspector General (IG) to cure. *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner*. 2015. IG Report No. 16-P-0019, Washington, D.C., *at* www.epa.gov/sites/production/files/2015-10/documents/20151027-16-p-0019.pdf.

Exemption to seeds coated with systemic insecticides, the agency is urged to grant the requests in this Petition within **180 days** of its filing date.<sup>9</sup>

#### **PETITIONERS**

The eleven Petitioners are listed below by three groups: 1) Beekeepers, 2) Farmers and 3) Public Interest Organizations. The Appendix, incorporated herein, describes their particularized interests.

**BEEKEEPER PETITIONERS:** Bret Adee, American Beekeeping Federation, American Honey Producers Association, Jeff Anderson, David Hackenberg, Pollinator Stewardship Council

FARMER PETITIONERS: Lucas Criswell, Gail Fuller

**PUBLIC INTEREST ORGANIZATION PETITIONERS**: American Bird Conservancy, Center for Food Safety (CFS), Pesticide Action Network of North America

#### **LEGAL BACKGROUND**

FIFRA governs pesticide commercialization and application in the United States. The definition of "pesticide" is (in pertinent part), a "mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u)(1). FIFRA makes it unlawful, with a few minor exceptions, for any "person in any State [to] distribute or sell to any person any pesticide that is not registered" under the Act. 7 U.S.C. § 136a(a); *see also* 7 U.S.C. § 136j(a)(1).

FIFRA prohibits EPA from registering a pesticide if its widespread and commonly recognized use would have "unreasonable adverse effects on the environment." 7 U.S.C § 136a(c)(5). EPA has broad discretion to require all data necessary to support the registration (including the conclusion that the pesticide will not have unreasonable adverse environmental effects), including testing of the product for effects on pollinators. *Id.* § 136a(c)(2)(A); *see e.g.*, 40 C.F.R. § 158.630.

<sup>&</sup>lt;sup>9</sup> EPA has refused to correct these failures regarding its exemption of systemic coated seeds despite prior oral and written requests to do so made by many of the Petitioners since at least 2015.

The Administrator is required to provide public notice and comment opportunities for registrations under 7 U.S.C. § 136a(c)(4):

Notice of application. The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

EPA's FIFRA-implementing regulations also contain procedural requirements for product registration, including, but not limited to, requiring publication of two classes of notices in the Federal Register. Under 40 C.F.R. § 152.102:

The Agency will issue in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the Federal Register a notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

The culmination of the registration process, if followed, is EPA's official approval of a label for the pesticide product, including use directions and appropriate warnings on safety and environmental risks. It is a violation of FIFRA for any person to sell or distribute a "misbranded" pesticide product. 7 U.S.C. § 136j(a)(1)(E). FIFRA is explicit in requiring EPA to find a product misbranded and, under 7 U.S.C. § 136(q)(1), may not be used, if:

- (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or]
- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment.

With regard to exemptions from FIFRA, the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. § 136w(b). EPA's implementing regulation for such exemptions, at 40 C.F.R. § 152.25, provides (in pertinent part; this is known as the Treated Article Exemption):

**Exemptions for pesticides of a character not requiring FIFRA regulation**. The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.

(a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

#### **FACTS**

#### I. Characteristics of Neonicotinoid-Coated Seeds.

The systemic nature of neonicotinoid-coated seeds renders them qualitatively and quantitatively different from other seeds. Seeds coated with liquid formulations of these chemicals are pesticide delivery devices. The purpose of this technology is to carry the active ingredient via the growing plants' circulatory systems into the tissues of the plants, which ultimately are typically hundreds or even thousands of times larger in dimension and mass than the seed itself. Common crops with neonicotinoid-coated seeds include, but are not limited to:

canola, field and sweet corn, cotton, cucurbits, legume vegetables, potatoes, soybean, sunflowers, and wheat.<sup>10</sup>

Given the lack of pesticide usage data collected by EPA, comprehensive data on the usage of clothianidin (most common product is Bayer CropScience's Poncho®), thiamethoxam (most common product is Syngenta's Cruiser®), and imidacloprid (most common product is Bayer and Valent USA's Gaucho®) have been scarce. However, EPA's preliminary risk assessments on those three neonicotinoid active ingredients released in January of 2017 revealed that 42 million to 61 million acres of corn are treated with clothianidin via seed coatings annually (45% to 65% of all U.S. corn acres) and 24 million to 42 million acres of corn are treated with thiamethoxam (26% to 45% of all U.S. corn acres). That means close to 100% of U.S. corn acres are likely treated with one of these two neonicotinoid insecticides.

In soybeans, 13 million to 21 million acres are treated with thiamethoxam (16% to 25% of all U.S. soybean acres), and 2.1 million acres are treated with clothianidin each year (3% of all U.S. soybean acres). Although the acreage of imidacloprid-treated soybean was not reported, EPA did report that 36% of all imidacloprid use is on soybeans as seed treatment, representing the largest increase in imidacloprid use from 2004-2013, from 300,000 to 400,000 pounds annually. EPA also included the usage data on imidacloprid from U.S. Geological Survey, indicating that over 800,000 pounds of imidacloprid were applied to soybeans in 2014. For comparison, that is nearly three times the amount of thiamethoxam applied to soybeans each

<sup>&</sup>lt;sup>10</sup> K. Stoner, Conn. Ag. Expt. Station, *Best Management Practices for Farmers Using Seeds Treated With Neonicotinoid Insecticides*. Unpublished report, *at* 

www.dem.ri.gov/programs/agriculture/documents/pwg\_docs\_seeds\_neonicotinoids.pdf.

<sup>&</sup>lt;sup>11</sup> EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, pp. 33-35, Tables 2.4 and 2.6 (Released Jan. 5, 2017), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-0173.

 $<sup>^{12}</sup>$  *Id*.

<sup>&</sup>lt;sup>13</sup> EPA, *Preliminary Aquatic Risk Assessment to Support Registration Review of Imidacloprid*, pp. 21-24 (Released Jan. 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1086.

<sup>14</sup> *Id.*, p. 23, Fig. 3-3.

year, which accounted for 13 million to 21 million acres. Thus, likely nearly 50% of soybean fields were planted with one of the neonicotinoid coatings.

While even less use data is publicly available for the other crops, EPA has stated in documents and legal filings that the estimated acreage planted with coated seeds amounts to at least 140 million acres nationally.<sup>15</sup> That is close to one-fifteenth of the entire land surface of the lower forty-eight states.<sup>16</sup>

The dried-on insecticidal coatings do not, in the vast majority of their uses, protect the seed itself against any disease or other risk to the seed. The neonicotinoid ingredients are predominately aimed at protecting the growing crop plants, later in time, as demonstrated by the EPA-approved labels placed on the bottles/containers of the liquid coating products. EPA is known to have approved fifteen new coating product registrations and their label language since January 1, 2010.<sup>17</sup> (See Table 1, *infra*.) All but two of those products (i.e., thirteen out of fifteen)

<sup>&</sup>lt;sup>15</sup> See n.1, supra.

<sup>&</sup>lt;sup>16</sup> U.S. land total from Land and Water Area of States, www.infoplease.com/ipa/A0108355.html.

<sup>&</sup>lt;sup>17</sup> The 15 coating products and initial labels are listed below; note that most of these products are labeled for more than one crop use (see Table 1, below): **1**. Prosper Evergol (date of first EPA label approval—May 11, 2012), *at* https://www3.epa.gov/pesticides/chem\_search/ppls/000264-01121-20120511.pdf; **2**. Poncho Votivo (date of first label approval—Mar. 16, 2010), *at* https://www3.epa.gov/pesticides/chem\_search/ppls/000264-01109-20100316.pdf; **3**. Emesto Quantum (date of first label approval—May 11, 2012), *at* 

https://www3.epa.gov/pesticides/chem\_search/ppls/000264-01125-20120511.pdf; **4.** INOVATE Seed Protectant (date of first label approval—June 21, 2011), *at* https://www3.epa.gov/pesticides/chem\_search/ppls/059639-00176-20110621.pdf; **5.** Sepresto 75 WS (date of first label approval—Apr. 28, 2010), *at* 

https://www3.epa.gov/pesticides/chem\_search/ppls/000264-01081-20100428.pdf; 6. NipsIt SUITE Cereals of Seed Protectant (date of first label approval—Dec. 21, 2011), at

https://www3.epa.gov/pesticides/chem\_search/ppls/059639-00183-20111221.pdf; 7. PONCHO/GB126 (date of first label approval—Apr. 29, 2011), at https://www3.epa.gov/pesticides/chem\_search/ppls/000264-01132-

<sup>20110429.</sup>pdf; 8. Helix Vibrance (date of first label approval—June 3, 2014), at

https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01528-20140603.pdf; 9. CruiserMaxx Potato Extreme (date of first label approval—June 12, 2013), at https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01444-20130612.pdf; 10. CruiserMaxx Vibrance (date of first label approval—Feb. 27, 2014), at

https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01508-20140227.pdf; **11**: Avicta Complete Beans 500 (date of first label approval—Jan. 15, 2013), at https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01457-20130115.pdf; **12**: SYT0511 (date of first label approval—Jan. 30, 2013), at

https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01460-20130130.pdf; **13**: SYT0113 (date of first label approval—Jan. 30, 2013), *at* https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01459-20130130.pdf; **14**: Cruiser Vibrance Quattro (date of first label approval—May 29, 2014), *at* 

https://www3.epa.gov/pesticides/chem\_search/ppls/000100-01527-20140529.pdf; 15: Dyna-shield Foothold Virock

lack a clear label claim that the neonicotinoid ingredient protects the planted seed itself; the labels generally state that the neonicotinoids are to kill "chewing and sucking insect pests" of the growing *plants*, not of the seeds. <sup>18</sup> (Several of the labels have unclear claims.) Moreover, the label warnings frequently indicate that the neonicotinoids actually may *harm* the seeds and result in reduced germination and/or reduction of seed and seedling vigor. <sup>19</sup> Depending on the crop, up to ninety percent of the insecticide is either scraped off the seeds and blown away as dust during machine planting, or sloughed off into the surrounding soil and groundwater. <sup>20</sup> In short, the alleged neonicotinoid "treatment" is predominately not "for the protection of the article itself"—the seed.

## **II.** The Treated Article Exemption.

The Treated Article Exemption, 40 C.F.R. § 152.25(a), was first promulgated in 1988. Pesticide-coated seeds were neither mentioned in the regulation text nor in the Federal Register notice accompanying the exemption. <sup>21</sup> In 2003, EPA publicly stated a view on the Treated Article Exemption and pesticide-coated seeds in a paper issued jointly by EPA and the Pest Management Regulatory Agency of Canada, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* (hereinafter "Harmonization Paper"). <sup>22</sup> The Harmonization Paper mentions pesticide-coated seeds, but it provides no coverage or analysis of systemic insecticide or neonicotinoid-coated seeds. Rather than supporting an interpretation that

<sup>(</sup>date of first label approval—Apr. 30, 2014), at https://www3.epa.gov/pesticides/chem\_search/ppls/034704-01090-20140430.pdf.

<sup>&</sup>lt;sup>18</sup> The exceptions are No. 1, Prosper Evergol, and No. 5 Sepresto 75 WS, above, the labels for which include at least one explicit *seed* protection claim for the neonicotinoid ingredient(s). Several other labels have unclear claims with respect to whether protection of the seed is provided by the neonicotinoid ingredients or other ingredients. Typically it is the *non*-neonicotinoid active ingredients that are claimed to protect the seed *per se*.

<sup>19</sup> *Id.* 

<sup>&</sup>lt;sup>20</sup> Goulson 2014, *supra*, n.4.

<sup>&</sup>lt;sup>21</sup> EPA, Pesticide Registration Procedures; Pesticide Data Requirements. Final Rule. 53 Fed. Reg. 15,977, May 4, 1988.

<sup>&</sup>lt;sup>22</sup> Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States April 11, 2003, pp. 1-2, (Joint Regulatory Directive of EPA and the Pest Management Regulatory Agency of Canada), perma.cc/3MUH-B9VQ.

systemic, neonicotinoid-coated seeds properly fit within the Treated Article Exemption described in 40 C.F.R. §152.25(a), the Harmonization Paper instead indicates that such coated seeds actually should be *excluded* from the exemption:

The term "for the protection of the [seed] itself' means that the pesticidal protection imparted to the treated seed *does not extend beyond the seed itself*...<sup>23</sup>

Clear and convincing evidence shows that the pesticidal "protective" effect of the scraped, blown, and sloughed-off neonicotinoid coatings "extends beyond the seed itself," and extends far beyond the full-grown plants. As explained more fully below, these harms stem from both the effects of the coatings that come off the seed and from the gross overuse of this systemic class of insecticides. Uncontained dust and contamination from these coatings is killing honey bees by the many millions and imposing a potentially catastrophic hazard to aquatic systems across the nation.<sup>24</sup> Both freshwater and marine systems and the invertebrate and vertebrate wildlife—such as fish and waterfowl—that they contain are being harmed. In addition to direct mortality to birds from ingesting neonicotinoid-coated seeds, indirect mortality is resulting from the destruction of rural invertebrate life across a vast portion of the United States.<sup>25</sup> Coated seeds are planted year after year and the active ingredients have long half-lives in most soils, exceeding the planting intervals. Thus, the contamination has swiftly built up to, and past, harmful levels in America's lands and waters.

<sup>&</sup>lt;sup>23</sup> *Id.* at 2 (emphasis added).

Morrissey, CA, Mineau, P., Devries, JH, Sanchez-Bayo, F., Liess, M, Cavallaro, MC, and Liber, K. 2015.
 Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review. *Environment International*, 74: 291-303; Sánchez-Bayo, F., Goka, K., and Hayasaka, D. 2016
 Contamination of the Aquatic Environment with Neonicotinoids and its Implication for Ecosystems. *Front. Environ. Sci. 4:71.* doi: 10.3389/fenvs.2016.00071, *at*: http://journal.frontiersin.org/article/10.3389/fenvs.2016.00071/full;
 Carnemark, M., Jenkins, P., and Walker, L. 2015. *Water Hazard: Aquatic Contamination by Neonicotinoid Insecticides in The United States.* Unpublished report, CFS, Washington, D.C., *at* www.centerforfoodsafety.org/files/neonic-water-report-final-242016\_web\_33288.pdf
 and Carnemark, M. *Water Hazard 2.0*, CFS, 2017.

The risks of the systemic insecticides appear to have not been foreseen by the registrants of the neonicotinoid liquid coating products or by EPA in applying its Treated Article Exemption to the coated seeds. The exemption has allowed these unregistered, unlabeled insecticides to outcompete and displace other *FIFRA-registered* insecticides and other less risky crop protection methods in U.S. agricultural markets. Their aggressive marketing has directly led to vastly more use of insecticides on crops for which no insecticides were needed or used by farmers in the years before these products were sold. This prophylactic use of coated seeds is incompatible with the principles of Integrated Pest Management.<sup>26</sup>

### III. EPA's Coating Product Approvals.

While exempting the various neonicotinoid-coated crop seeds themselves, EPA has approved and registered the liquid coating products to be applied to seeds in a facility before sale or in limited cases by farmers themselves. However, EPA has failed to fully assess the adverse effects, described in this Petition, of the systemic insecticide beyond the seed coating process. Table 1 indicates unregistered pesticidal crop seeds with fifteen coating products that EPA approved since January 1, 2010.<sup>27</sup>

<sup>&</sup>lt;sup>26</sup> Iowa State University, et al. 2015. *The Effectiveness of Neonicotinoid Seed Treatments in Soybean*. Unpublished extension report, *at* www.extension.umn.edu/agriculture/soybean/pest/docs/effectiveness-of-neonicotinoid-seed-treatments-in-soybean.pdf.

<sup>&</sup>lt;sup>27</sup> See labels listed in n.17, *supra*.

**Table 1: Unregistered Pesticidal Crop Seeds Approved Since 2010.** 

Active Ingredient	Coating Product	Pesticidal Crop Seeds			
Clothianidin					
	Prosper Evergol	Canola, rapeseed and mustard			
	Poncho Votivo/ Poncho 1250	Corn, cotton, sorghum, soybean and			
	Votivo	sugarbeet			
	Ernesto Quantum	Cotton			
	Inovate	Soybean			
	Sepresto 75 WS	Barley, buckwheat, corn, millet, oats, popcorn, rye, sorghum, teosinte, triticale, wheat, potato seed pieces, carrot, onion bulbs, leek, bunching onion, and broccoli			
	NipsIt Suite Cereals Seed Protectant	Barley, oat and wheat			
	Poncho/GB126	Sugarbeet, barley, buckwheat, millet, oats, rye, teosinte, triticale and wheat			
Thiamethoxam					
	Helix Vibrance	Canola			
	CruiserMAXX Potato Extreme	Potato			
	CruiserMAXX Vibrance	Soybean			
	Avicta Complete Beans	Soybean			
	SYT0511 and SYT0113	Soybean			
	Cruiser Vibrance Quattro	Small grain cereals			
Imidacloprid					
	Dynashield Foothold Virock	Barley and wheat			

Source: EPA Pesticide Product and Label System database, at

https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

This Petition addresses all such pesticidal seeds, including both those listed in Table 1 and other older or newer pesticidal seeds products not listed in Table 1. The number of different crops in Table 1 totals at least twenty-five. The seeds are sold by various marketers under a large variety of product line names or numbers that typically, but not always, include the seed coatings.<sup>28</sup>

EPA's Risk Assessments (RAs) for the coating products ignore numerous risks of planting the resulting seeds, such as the toxic abraded dust-off, due to EPA's inclusion of the

<sup>&</sup>lt;sup>28</sup> A non-exhaustive sample list includes: 1) Wyffels Hybrid corn lines W1526RIB; 1528RIB; and W1690, shipped coated with Poncho, *see* perma.cc/9N92-QAC5; and 2) the Pioneer Brand T Series of soybean seeds coated with Pioneer Premium Seed Treatment, *see* perma.cc/R8X8-FV9A.

coated seeds themselves under the Treated Article Exemption. This is most vividly illustrated in EPA's 2016 *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid*.<sup>29</sup> It discloses that: "Mitigation of risks from abraded seed coating are addressed *outside* of this process." The identical assertion that EPA's risk assessors are not actually analyzing the external effects and risks of the abraded coatings is repeated in the Preliminary RAs for both thiamethoxam and clothianidin.<sup>30</sup> The Agency's claims that the risks are addressed "outside of" the formal RA process are not supported by any evidence.

Further, the large majority of the coating products listed in Table 1 were "conditionally registered" under FIFRA, indicating that key information needed for their full risk evaluation was not produced by the registrants to allow an unconditional registration.<sup>31</sup> Extensive information gaps remain for the resulting coated seeds.

### IV. Major Reviews and Studies on Harms of Coated Seeds.

The full scope of harms have been revealed by extensive scientific monitoring and analysis, including an authoritative 2014 global review of over 800 published studies conducted under the auspices of the International Union for the Conservation of Nature (IUCN).<sup>32</sup> That expert review determined that neonicotinoids were dangerously overused and should be restricted. Based on detailed assessments by the European Food Safety Agency (EFSA), the European Union (EU) voted to prohibit their use on seeds of most crops largely due to dust-off

<sup>&</sup>lt;sup>29</sup> EPA-HQ-OPP-2008-0844-0140, p. 36, lower left corner of Fig. 2-5 "Tiered approach for assessing risk to honey bees from soil/seed applications," (Released Jan. 6, 2016), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0140.

<sup>&</sup>lt;sup>30</sup> EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, p. 46, lower left corner of Fig. 2-5 "Tiered approach for assessing risk to honey bees from soil/seed applications," (Released Jan. 5, 2017), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-0173.

<sup>&</sup>lt;sup>31</sup> Conditional registration requires the registrants to meet EPA's conditions regarding missing data, such as to conduct studies to fill specific data gaps, within a set timeframe. 7 U.S.C. § 136a(c)(7)(C).

<sup>&</sup>lt;sup>32</sup> Van der Sluijs J.P., et al., 2014. Conclusions of the Worldwide Integrated Assessment on the risks of neonicotinoids and fipronil to biodiversity and ecosystem functioning, Environ. Sci. Pollut. Res. 22 (1), 148-154, at perma.cc/7RVA-FMA7.

and other harmful effects on bees.<sup>33</sup> That prohibition has been in effect since the EU vote in 2013.

In a 2017 review and update of the evidence that EFSA considered, Wood and Goulson published the comprehensive *Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013*.<sup>34</sup> Examining eight risk topics, the authors sought "to summarize how the new evidence has changed our understanding of the likely risks to bees; is it lower, similar or greater than the risk perceived in 2013"? The study vindicated the EU's 2013 prohibition, finding no decreased risk for any topics. For six risk topics they found them to be "Risk Unchanged." Evidence for the two topics connected with seed coatings pointed to a "Greater Risk." Wood and Goulson also found extensive new evidence of what they labeled "broader risks to environmental health" that were not fully understood in 2013. They concluded:

Field-realistic laboratory experiments and field trials continue to demonstrate that traces of residual neonicotinoids can have a mixture of lethal and sublethal effects on a wide range of taxa. . . . Relative to the risk assessments produced in 2013 for clothianidin, imidacloprid and thiamethoxam which focused on their effects on bees, new research strengthens arguments for the imposition of a moratorium, in particular because it has become evident that they pose significant risks to many non-target organisms, not just bees.

Acting to protect wildlife on Refuges, the U.S. Fish and Wildlife Service (FWS) prohibited all neonicotinoids from use in all National Wildlife Refuges as of January 1, 2016, because the Service: <sup>36</sup>

<sup>&</sup>lt;sup>33</sup> Official Journal of the European Union, Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013, amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, L 139/12; 25.5.2013, *at* http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:139:0012:0026:EN:PDF.

Wood, T.J. and Goulson, D. 2017. *The Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013*. Unpublished report for Greenpeace. Paris, France, *available at http://www.greenpeace.org/international/global/international/publications/agriculture/2017/neonicotinoid-pesticides.pdf*.

<sup>&</sup>lt;sup>35</sup> Wood and Goulson 2017, *supra*, p. 8. The two "Greater Risk" findings are for these topic areas: "Risk of exposure from and uptake of neonicotinoids in non-crop plants" and "Sublethal effects of neonicotinoids on wild bees."

<sup>36</sup> Memorandum from James W. Kurth, Chief, National Wildlife Refuge System, U.S. Department of the Interior, Fish and Wildlife Service, *Use of Agricultural Practices in Wildlife Management in the National Wildlife Refuge* 

. . . determined . . . prophylactic use, such as a seed treatment, of the neonicotinoid pesticides that can distribute systematically in a plant and can potentially affect a broad spectrum of non-target species.

The FWS also has found that these seeds are among the neonicotinoid uses that are "strongly implicated" as a factor in the "endangered" classification under the ESA that the agency gave to the once-common Rusty Patched Bumble Bee.<sup>37</sup> The agency stated (citations omitted; emphasis added):<sup>38</sup>

Neonicotinoids are a class of insecticides used to target pests of agricultural crops, forests (for example, emerald ash borer), turf, gardens, and pets and have been strongly implicated as the cause of the decline of bees in, and specifically for rusty patched bumble bees, due to the contemporaneous introduction of neonicotinoid use and the precipitous decline of the specie. . . . The use of neonicotinoids rapidly increased as seed-applied products were introduced in field crops, marking a shift toward large-scale, preemptive insecticide use.

A major review by the American Bird Conservancy stated that a *single* corn kernel treated with any of the common neonicotinoids could kill a songbird and just one-tenth of a treated corn kernel is enough to adversely affect a songbird's reproduction.<sup>39</sup>

Peer-reviewed, published studies from just the last two years further illustrate harmful effects from these coated seeds, effects that EPA's RAs for the coating chemicals have failed to assess. A list of the studies and excerpts of their abstracts follows:

1) Alburaki et al. 2015. 40 Indicating that neonicotinoid exposures increase pathogen risks

System 1 (July 17, 2014), at www.centerforfoodsafety.com/files/agricultural-practices-in-wildlife-management 20849.pdf.

<sup>&</sup>lt;sup>37</sup> Department of the Interior, U.S. Fish and Wildlife Service. Final rule, Endangered Species Status for Rusty Patched Bumble Bee, 82 Fed. Reg. 3,186, January 11, 2017, *at* 

https://www.fws.gov/midwest/endangered/insects/rpbb/pdf/FRF in alListing Rule RPBB 11 Jan 2017. pdf

<sup>&</sup>lt;sup>38</sup> *Id.*, at p. 3,190; see also p. 3,201.

<sup>&</sup>lt;sup>39</sup> Mineau, P. and Palmer, C. 2013. *The Impact of the Nation's Most Widely Used Insecticides on Birds*. American Bird Conservancy, *at*: www.abcbirds.org/abcprograms/policy/toxins/Neonic FINAL.pdf.

and weaken honey bee colonies:

Thirty-two honeybee (Apis mellifera) colonies were studied in order to detect and measure potential in vivo effects of neonicotinoid pesticides used in cornfields (Zea mays spp) on honeybee health . . . Hives were extensively monitored for their performance and health traits over a period of two years. Honeybee viruses (brood queen cell virus BQCV, deformed wing virus DWV, and Israeli acute paralysis virus IAPV) and the brain specific expression of a biomarker of host physiological stress, the Acetylcholinesterase gene AChE, were investigated using RTqPCR . . . In addition, general hive conditions were assessed by monitoring colony weight and brood development. Neonicotinoids were only identified in corn flowers at low concentrations. However, honeybee colonies located in neonicotinoid treated cornfields expressed significantly higher pathogen infection than those located in untreated cornfields. AChE levels showed elevated levels among honeybees that collected corn pollen from treated fields. Positive correlations were recorded between pathogens and the treated locations. Our data suggests that neonicotinoids indirectly weaken honeybee health by inducing physiological stress and increasing pathogen loads.

**Botias et al. 2016.** Seed-coating of canola with neonicotinoids in the UK led to frequently high-level contamination of marginal vegetation:

...we analysed samples of foliage collected from neonicotinoid seed-treated oilseed rape plants and also compared the levels of neonicotinoid residues in foliage (range: 1.4-11 ng/g) with the levels found in pollen collected from the same plants (range: 1.4-22 ng/g). We then analysed residue levels in foliage from nontarget plants growing in the crop field margins (range: ≤0.02-106 ng/g). Finally, in order to assess the possible risk posed by the peak levels of neonicotinoids that we detected in foliage for farmland phytophagous and predatory insects, we compared the maximum concentrations found against the LC50 values reported in the literature for a set of relevant insect species. Our results suggest dressings lead to that neonicotinoid seed widespread contamination of the foliage of field margin plants with mixtures of neonicotinoid residues, where levels are very variable and

Alburaki, M., Boutin, S., Mercier, PL, Loublier, Y., Chagnon, M., and Derome, N. 2015. Neonicotinoid-coated *Zea mays* seeds indirectly affect honeybee performance and pathogen susceptibility in field trials. *Plos One*, 10(5): p.e0125790, doi:10.1371/journal.pone.012579 (emphasis added).
 Botías, C., David, A., Hill, EM, and Goulson, D., 2016. Contamination of wild plants near neonicotinoid

<sup>&</sup>lt;sup>41</sup> Botías, C., David, A., Hill, EM, and Goulson, D., 2016. Contamination of wild plants near neonicotinoid seed-treated crops, and implications for non-target insects. *Science of the Total Environment*, 566: 269-278 (emphasis added).

discontinuous, but sometimes overlap with lethal concentrations reported for some insect species.

David et al. 2016.<sup>42</sup> Marginal vegetation near treated-seed canola fields was contaminated with high levels of neonicotinoids and other chemicals with synergistic effects:

Here, we quantify concentrations of neonicotinoid insecticides and fungicides in the pollen of oilseed rape, and in pollen of wildflowers growing near arable fields. We then compare this to concentrations of these pesticides found in pollen collected by honey bees and in pollen and adult bees sampled from bumble bee colonies placed on arable farms. We also compared this with levels found in bumble bee colonies placed in urban areas. Pollen of oilseed rape was heavily contaminated with a broad range of pesticides, as was the pollen of wildflowers growing nearby. Consequently, pollen collected by both bee species also contained a wide range of pesticides, notably including the fungicides carbendazim, boscalid, flusilazole, metconazole, tebuconazole and trifloxystrobin and the neonicotinoids thiamethoxam, thiacloprid and imidacloprid. . . It is notable that pollen collected by bumble bees in rural areas contained high levels of the neonicotinoids thiamethoxam (mean 18 ng/g) and thiacloprid (mean 2.9 ng/g), along with a range of fungicides, some of which are known to act synergistically with neonicotinoids.

4) Millot et al.<sup>43</sup> Review of bird mortalities in France documented a high proportion resulted from common farmland birds consuming neonicotinoid-coated seeds:

The large-scale use of neonicotinoid insecticides has raised growing concerns about their potential adverse effects on farmland birds, and more generally on biodiversity. Imidacloprid, the first neonicotinoid commercialized, has been identified as posing a risk for seed-eating birds when it is used as seed treatment of some crops since the consumption of a few dressed seeds could cause mortality. But evidence of direct effects in the field is lacking. Here, we reviewed the 103 wildlife mortality incidents reported by

<sup>&</sup>lt;sup>42</sup> David, A., Botías, C., Abdul-Sada, A., Nicholls, E., Rotheray, EL, Hill, EM, and Goulson, D., 2016. Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops. *Environment International*, 88: 169-178 (emphasis added).

<sup>&</sup>lt;sup>43</sup> Millot, F., Decours, A. *et al.*, 2016. Field evidence of bird poisonings by imidacloprid-treated seeds: a review of incidents reported by the French SAGIR network from 1995 to 2014 Environ *Sci Pollut Res* DOI 10.1007/s11356-016-8272-y (emphasis added).

the French SAGIR Network from 1995 to 2014, for which toxicological analyses detected imidacloprid residues. One hundred and one incidents totalling at least 734 dead animals were consistent with an agricultural use as seed treatment. Grey partridges (Perdix perdix) and "pigeons" (Columba palumbus, Columba livia and Columba oenas) were the main species found. More than 70% of incidents occurred during autumn cereal sowings. Furthermore, since there is no biomarker for diagnosing neonicotinoid poisonings, we developed a diagnostic approach to estimate the degree of certainty that these mortalities were due to imidacloprid poisoning. By this way, the probability that mortality was due to poisoning by imidacloprid treated seeds was ranked as at least "likely" in 70% of incidents. As a result, this work provides clear evidence to risk managers that lethal effects due to the consumption by birds of imidacloprid-treated seeds regularly occur in the field. This in turn raises the question of the effectiveness of the two main factors (seed burying and imidacloprid-treated seeds avoidance) that are supposed to make the risk to birds negligible.

Mogren and Lundgren. 2016.<sup>44</sup> Set-aside vegetation strips near farms did not protect bees from nutritional harms caused by adjacent corn fields planted with clothianidin-coated seeds:

Pollinator strips were tested for clothianidin contamination in plant tissues, and the risks to honey bees assessed. An enzyme-linked immunosorbent assay (ELISA) quantified clothianidin in leaf, nectar, honey, and bee bread at organic and seed-treated farms. Total glycogen, lipids, and protein from honey bee workers were quantified. The proportion of plants testing positive for clothianidin were the same between treatments. Leaf tissue and honey had similar concentrations of clothianidin between organic and seed-treated farms. Honey (mean  $\pm$ SE: 6.61  $\pm$  0.88 ppb clothianidin per hive) had seven times greater concentrations than nectar collected by bees  $(0.94 \pm 0.09 \text{ ppb})$ . Bee bread collected from organic sites (25.8  $\pm$  3.0 ppb) had significantly less clothianidin than those at seed treated locations (41.6  $\pm$  2.9 ppb). Increasing concentrations of clothianidin in bee bread were correlated with decreased glycogen, lipid, and protein in workers. This study shows that small, isolated areas set aside for conservation do not provide spatial or temporal relief from

<sup>&</sup>lt;sup>44</sup> Mogren, CL and Lundgren, JG, 2016. Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status. *Scientific Reports*, 6:29608; DOI: 10.1038/srep29608 (emphasis added).

neonicotinoid exposures in agricultural regions where their use is largely prophylactic.

**Rundlof et al. 2015.** Harm to wild bumblebees and other wild bees (which mostly are solitary) from clothianidin-coated canola seeds in a major field study in Sweden, published in *Nature*:

Here we show that a commonly used insecticide seed coating in a flowering crop can have serious consequences for wild bees. In a study with replicated and matched landscapes, we found that seed coating with Elado, an insecticide containing a combination of the neonicotinoid clothianidin and the non-systemic pyrethroid b-cyfluthrin, applied to oilseed rape seeds, reduced wild bee density, solitary bee nesting, and bumblebee colony growth and reproduction under field conditions. Hence, such insecticidal use can pose a substantial risk to wild bees in agricultural landscapes, and the contribution of pesticides to the global decline of wild bees may have been underestimated. The lack of a significant response in honeybee colonies suggests that reported pesticide effects on honeybees cannot always be extrapolated to wild bees.

7) Woodcock et al. 2016.<sup>46</sup> Planting neonicotinoid-treated canola seed is an important factor in the *extinction* of wild bee species in Britain:

We relate 18 years of UK national wild bee distribution data for 62 species to amounts of neonicotinoid use in oilseed rape. Using a multi-species dynamic Bayesian occupancy analysis, we find evidence of increased population extinction rates in response to neonicotinoid seed treatment use on oilseed rape. Species foraging on oilseed rape benefit from the cover of this crop, but were on average three times more negatively affected by exposure to neonicotinoids than non-crop foragers. Our results suggest that sub-lethal effects of neonicotinoids could scale up to cause losses of bee biodiversity. Restrictions on neonicotinoid use may reduce population declines.

<sup>&</sup>lt;sup>45</sup> Rundlöf, M., Andersson, GK, Bommarco, R., Fries, I., Hederström, V., Herbertsson, L., Jonsson, O., Klatt, BK, Pedersen, TR, Yourstone, J., and Smith, HG, 2015. Seed coating with a neonicotinoid insecticide negatively affects wild bees. *Nature*, 521(7550): 77-80. (emphasis added).

<sup>&</sup>lt;sup>46</sup> Woodcock, BA, NJ Isaac, JM Bullock, DB Roy, DG Garthwaite, A Crowe, and RF Pywell. 2016. Impacts of neonicotinoid use on long-term population changes in wild bees in England. *Nature Communications*, 7: 12459 (emphasis added).

## V. Honey Bee Kills and Other Costs.

Pervasive use of these chemicals, particularly on corn and soybeans, is resulting in pesticide contamination of vast areas extending far beyond the planted fields. Many beekeepers have observed toxic dust clouds billowing from seed planting machines, spreading the insecticides far and wide: to neighboring farms, onto marginal vegetation visited by their bees, into waterways, and even directly onto their beehives. Honey bee kill incidents caused by neonicotinoid-coated seeds have numbered in the hundreds and likely many more. These incidents have likely killed hundreds of millions of individual bees due to acute dust-off kills and chronic damage to bee hives. As a result, for Beekeeper Petitioners Anderson, Adee, and Hackenberg and other beekeepers represented by Petitioners American Beekeeping Federation, American Honey Producers Association and Pollinator Stewardship Council, their honey production and the overall profitability of their business have drastically declined, while their workloads and personal stress have multiplied.

A recent scientific study from England showed high and unexpected contamination in honey bee hives resulting from seed coatings, originating with contaminated marginal vegetation near the canola fields rather than from the canola pollen. Honey bees examined in the study were collecting enough neonicotinoids to damage their productivity and reproduction rate. Similarly, a Canadian study found unexpectedly high levels of neonicotinoids in the surface dust of arable fields and evidence that this dust blows into adjoining fields, contaminating them and

<sup>&</sup>lt;sup>47</sup> For a source on beekills that is not comprehensive but is illustrative of the problem, see Pollinator Stewardship Council, Reported Bee Kills, at http://pollinatorstewardship.org/?page\_id=1428. Beekeepers typically do not report their dust-off kills systematically as there are no Federal or State enforcement responses due to the exemption that is the focus of this Petition.

<sup>&</sup>lt;sup>48</sup> Botias, *et al.*, 2015. Neonicotinoid rresidues in wwildflowers, a ppotential rroute of cchronic cexposure for bees, *Environ. Sci. Technol.* 49(21): 12731-12740, *available at* perma.cc/G2PY-UF25.

putting surface-living beneficial species at risk. 49 Sublethal doses can result in honey bee colony damage through chronic effects, including compromising the behavior, health, and immunity of colonies, thus causing them to collapse under the additional stress of pathogens and parasites.<sup>50</sup>

The costs of neonicotinoid-coated seeds and their resulting contamination include, at a minimum, these foreseeable categories: 1) harmful honey bee colony effects and resulting reduced yields of pollinated crops; 2) reduced production of honey and other bee products; 3) financial harm to beekeepers and consumers; 4) loss of ecosystem services; and 5) market damage from contamination events.<sup>51</sup> Estimated cumulative, direct, and indirect costs of this contamination to date across these five categories are in the tens of billions of dollars. 52 The Beekeeper Petitioners have personally experienced many of the economic harms associated with bee kills and the decline of pollinators, as stated in the Interests of the Petitioners in the Appendix.

The harm to native bees, which are essential pollinators but that lack commercial valuation, is nationwide and incalculable. Unmanaged and often living in contaminated soil, species such as bumblebees, ground-nesting mining bees, alkali bees, squash bees, and long-horned sunflower bees are harmed by repeated, persistent use of the coated seeds. Adverse impacts to other species of native bees that are not ground nesters also has been identified, particularly due to the high toxicity of neonicotinoids to blue orchard bees and alfalfa leafcutter

<sup>&</sup>lt;sup>49</sup> Victor Limay-Rios, et al., 2015. Neonicotinoid insecticide residues in soil dust and associated parent soil in fields with a history of seed treatment use on crops in Southwestern Ontario, Environ. Toxicol. Chem. 35(2):303-10. doi: 10.1002/etc.3257, available at perma.cc/4PTA-HQRN.

<sup>&</sup>lt;sup>50</sup> Dussaubat, C., Maisonnasse, A., Crauser, D., Tchamitchian, S., Bonnet, M., Cousin, M., Kretzschmar, A., Brunet, JL, and Le Conte, Y., 2016. Combined neonicotinoid pesticide and parasite stress alter honeybee queens' physiology and survival. Scientific Reports, 6:31430; DOI: 10.1038/srep31430; Sánchez-Bayo, F., Goulson, D., Pennacchio, F., Nazzi, F., Goka, K., and Desneux, N., 2016. Are bee diseases linked to pesticides?—a brief review. Environment International, 89:7-11.

<sup>&</sup>lt;sup>51</sup> Stevens S., and Jenkins, P., 2014. Heavy Costs: Weighing the Value of Neonicotinoid Insecticides in Agriculture. Unpublished report, CFS, Washington, D.C., pp. 12-15, at http://www.centerforfoodsafety.org/files/neonicefficacy\_digital\_29226.pdf. <sup>52</sup> *Id*.

bees.<sup>53</sup> While blue orchard and leafcutter bees do not nest in the soil, they rely on plant materials and mud for building their brood cells and can be contaminated through those nesting materials and other exposure routes. None of the risks to native bees are captured in EPA's Pollinator RAs issued in 2016 and 2017 for the three main active ingredients in the seed coating products: imidacloprid, clothianidin and thiamethoxam.

#### VI. Harm to Threatened and Endangered Species.

The sum lesson of the voluminous science cited throughout this Petition is that the pesticidal coated-seeds may affect broad groups of non-target animals. These range from direct harm to both managed and wild bees and other beneficial terrestrial insects, to contaminated run-off decimating aquatic invertebrates, to both acute and chronic effects on birds that ingest the seeds. Within each of those animal groups are many threatened and endangered species protected under the ESA. The 2017 listing of the rusty patched bumble bee, mentioned above, is one example of species listed partially because it is directly affected by the use of neonicotinoid coated seeds. Two butterflies listed in 2014 also had neonicotinoid-coated seeds explicitly singled out by the FWS as a significant factor that led to their listings: Dakota skipper (*Hesperia dacotae*) and Poweshiek skipperling (*Oarisma poweshiek*).<sup>54</sup>

Nationally and internationally recognized experts, Drs. John Stark of Washington State University, John Losey of Cornell University, and Pierre Mineau, a consultant formerly with Environment Canada, have submitted formal expert opinions identifying at least these five

<sup>&</sup>lt;sup>53</sup> Hopwood, J., Code, A., Vaughan, M., Biddinger, D., Shepherd, M., Black, S.H., Mader, E., and Mazzacano, C., 2016 *How Neonicotinoids Can Kill Bees* 2d Ed., Unpublished report, Xerces Society for Invertebrate Conservation, Portland, OR, *at* www.xerces.org/wp-content/uploads/2016/10/HowNeonicsCanKillBees\_XercesSociety Nov2016.pdf.

<sup>&</sup>lt;sup>54</sup> 79 Fed. Reg. 63,672 (Oct. 24, 2014)(codified at 50 C.F.R. pt. 17), available at https://www.fws.gov/midwest/endangered/insects/dask/pdf/FRButterflyFinalListing24Oct2014.pdf.

additional ESA-protected species, beyond the two butterflies above (which they also identified), as potentially affected by coated seed use:<sup>55</sup>

**Invertebrates:** Hine's emerald dragonfly (*Somatochlora hineana*); Salt Creek tiger beetle (*Cicindela nevadica lincolniana*).

**Birds:** Mississippi sandhill crane (*Grus canadensis pulla*), whooping crane (*Grus Americana*), Attwater's prairie chicken (*Tympanuchus cupido attwateri*).

The analyses by Drs. Stark, Losey, and Mineau focused just on a small number of case study species (three species per expert). They stated in their opinions that likely many other similarly-exposed ESA-listed species could be affected.<sup>56</sup> The following is an illustrative, non-exhaustive, list of ten threatened and endangered terrestrial insects that EPA should consider as an additional starting point:<sup>57</sup>

1) American burying beetle (Nicrophorus americanus); 2) Behren's fritillary (or Behren's silverspot) (Speyeria zerene behrensii); 3) Callippe silverspot (Speyeria callippe callippe); Fender's blue (Icaricia icarioides fender); 4) Karner blue (Plebejus melissa samuelis); 5) Lange's metalmark (Apodemia mormo langei); 6) Mitchell's satyr butterfly Neonympha mitchellii mitchelli; 7) Myrtle's silverspot (Speyeria zerene myrtleae); 8) Quino checkerspot butterfly (Euphydryas editha quino); 9) San Bruno elfin (Callophrys mossii bayensis); and 10) Schaus swallowtail (Papilio aristodemus ponceanus).

As discussed in the Argument section, below, EPA has never once consulted with the expert agencies—the FWS or National Marine Fisheries Service (NMFS)—on any neonicotinoid insecticide product registration or on the exempted coated seeds as required under the ESA when

<sup>&</sup>lt;sup>55</sup> Expert Declarations of Drs. John Stark, John Losey, and Pierre Mineau, filed with this Petition; these were originally prepared in support of Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Summary Judgment, *Ellis v. Housenger*, No. 3:13-cv-01266-MMC, ECF No. 215-1 (N.D. Cal. Apr. 14, 2016).

<sup>&</sup>lt;sup>56</sup> Decl. Mineau ¶¶ 9, 23, 43, 45; Decl. Stark ¶¶ 17, 49; Decl. Losey ¶ 8, 10, 12, 14.

<sup>&</sup>lt;sup>57</sup> See listings in FWS ECOS Environmental Conservation Online System, http://ecos.fws.gov/ecp0/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=
T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAT&mapstatus=3&fcrithab=on &fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. This list will need updating as more species are regularly added and numerous "Candidate" species await further action.

"effects" on any listed species or their critical habitats are foreseeable. Since ninety-five percent of the land area in the country that is affected by any neonicotinoid product is affected by the coated seeds, obviously consultation on the seeds' effects is required. The more than 140 million acres planted across the country overlaps the habitats of, or otherwise affects, literally *hundreds* of listed species. EPA's own internal risk assessments for various seed treatment uses of clothianidin and thiamethoxam going back at least seventeen years explicitly reveal that the agency is fully aware that likely many hundreds of species may be affected.<sup>58</sup>

The *obvious* failures to date are the three ESA-listed species for which the planting of neonicotinoid-coated seeds already are labeled by the FWS as significant factors in their listings, again, the rusty patched bumble bee, Dakota skipper and Poweshiek skipperling. EPA's ongoing

<sup>&</sup>lt;sup>58</sup> The following 13 risk assessments and similar documents are illustrative of numerous documents in EPA's own files just for clothianidin and thiamethoxam that show foreseeable effects of the coated seeds on hundreds of ESA-listed species nationwide. This is not exhaustive. As EPA has copies of its own very lengthy assessments, copies are not being attached with this Petition:

<sup>1)</sup> Clothianidin Pesticide Fact Sheet, dated May 30, 2003.

EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola, dated Feb. 20, 2003.

<sup>3) &</sup>quot;Addendum" to the above-referenced EFED Risk Assessment, dated Apr. 10, 2003.

<sup>4)</sup> EFED Registration Chapter for Clothianidin for Use on Potatoes and Grapes as a spray treatment and as a Seed Treatment for Sorghum and Cotton, dated Sept. 28, 2005.

<sup>5)</sup> Revised Assessment for Clothianidin Registration of Prosper T400 Seed Treatment on Mustard Seed and Poncho/Votivo Seed Treatment on Cotton, dated Dec. 2, 2010.

<sup>6)</sup> Environmental Fate and Ecological Risk Assessment for the Use of Thiamethoxam as a Seed Treatment to Control Grape Colapsis on Arkansas Rice, dated Feb. 26, 2009.

<sup>7)</sup> Ecological Risk Assessment for the Proposed New Uses of Thiamethoxam Seed Treatment for Dry Bulb Onions and Peanuts and Registered Seed Treatment for Corn, Carrots, Leafy Vegetables, and Brassica (Cole) Leafy Vegetables, dated May 18, 2010.

<sup>8)</sup> Ecological Risk Assessment for the Proposed New Uses of Thiamethoxam Seed Treatment on Alfalfa, dated Dec. 28, 2010.

<sup>9)</sup> Environmental Fate and Ecological Risk Assessment for the Registration of Thiamethoxam On Ornamentals, Brassica (Cole) and Non-Brassica Leafy Vegetables, Pecans, Succulent Beans, Sunflower, and Stone fruit, dated June 1, 2009.

<sup>10)</sup> Section 3 Registration Request for Use of Thiamethoxam on Multiple Crops, dated June 11, 2001.

<sup>11)</sup> Section 3 Registration Request for Thiamethoxam (Chemical #060109, DP Barcode D251956) Use as a Seed Treatment, dated Dec. 14, 2000.

<sup>12)</sup> Ecological Risk Assessment for the Proposed New Use of Thiamethoxam as a Seed Treatment for Cereal Grains, dated Aug. 30, 2011.

<sup>13)</sup> Ecological Risk Assessment for the Section 3 New Use Registration of Thiamethoxam on Tropical Fruits, Sugar Beet Seed, Rice Seed, Cranberry, Bushberry Subgroup 13-07B, Low Growing Berry Subgroup 13-07G, Caneberry Subgroup 13-07A, and Small Fruit Vine Climbing Subgroup 13, dated May 18, 2009.

refusal to consult under the ESA must change or else these—and other—valued, irreplaceable, native species may face severe jeopardy of extinction now directly under the agency's watch.

#### VII. Lack of Yield Benefits.

Two thorough reviews of the published science on crop yields by Petitioner Center for Food Safety (CFS), first in 2014 and then updated in 2016, show that use of neonicotinoid-coated seeds actually provides no net yield benefit to farmers across the majority of cropplanting contexts. <sup>59</sup> The 2016 report *Net Loss* report summarizes the current knowledge:

[T]he broad lack of independent data showing economic justification for [neonicotinoids] use on seeds indicates that they are grossly over-used. In the European Union (EU), there is no evidence that crop production declined due to the 2013 prohibition on most crop-seed uses of neonicotinoids, which was adopted across the continent despite extremely dire industry predictions made at the time. In fact, on average, production to date has risen for major crops. Thus, prohibiting use of the neonicotinoid seed coatings did not deny European farmers any significant economic benefits.

Further, agricultural scientists and other experts in the United States and the United Kingdom have issued extensive new studies and reviews on the lack of overall efficacy of this technology. The lack of economic justification for the prophylactic use of neonicotinoid-coated seeds for soybeans (the second most extensively planted U.S. crop after corn), is virtually uncontested based on the overwhelming weight of independent reviews. Published evidence on weak or non-existent benefits exists for other crops as well, although it is more sporadic.

The most detailed report on the "efficacy" question for soybeans came from EPA itself, issued in 2015.<sup>60</sup> The Agency's Biological and Economic Analysis Division (BEAD) stated:

<sup>&</sup>lt;sup>59</sup> Stevens and Jenkins, 2014, *supra*; Jenkins, P., *Net Loss—Economic Efficacy and Costs of Neonicotinoid Insecticides Used as Seed Coatings: Updates from the United States and Europe* (2016), unpublished report, CFS, Washington, D.C., *at* www.centerforfoodsafety.org/files/efficacy-netloss12616 38208.pdf.

<sup>&</sup>lt;sup>60</sup> Myers, C., Hill, E., *Memorandum: Benefits of Neonicotinoid Seed Treatments to Soybean Production* at 9, United States Environmental Protection Agency (Oct. 15, 2014), *at* www.epa.gov/sites/production/files/2014-10/documents/benefits of neonicotinoid seed treatments to soybean production 2.pdf.

This analysis provides evidence that U.S. soybean growers derive limited to no benefit from neonicotinoid seed treatments in most instances. Published data indicate that most usage of neonicotinoid seed treatments does not protect soybean yield any better than doing no pest control. Given that much of the reported seed treatment usage in the U.S. on soybeans is not associated with a target pest, BEAD concludes that much of the observed use is preventative and may not be currently providing any actual pest management benefits.

BEAD went on to observe, based on EPA's survey of agriculture extension experts nationwide, that when asked how the use of neonicotinoid-treated seeds affected soybean yields, *seventy-four percent* of respondents stated that *yield either stayed the same or decreased*. EPA must heed its own analysis. The lack of yield benefits in most cases, and actual yield *reductions* in many cases, reinforces the experience of the Farmer Petitioners Criswell and Fuller. Despite paying for the seed coating protections when they bought seeds in the past, the farmers' yields did not benefit. And the beneficial insects in or near their farms and other aspects of their soil health were harmed. 62

#### VIII. Aquatic Contamination.

Recent studies address the severe aquatic contamination associated with neonicotinoids, which are water soluble. Their increasing contamination of ditches, streams, groundwater, lakes, rivers, and marine areas is now being documented. Researchers across the United States are finding high levels, exceeding vital standards set by experts to protect aquatic life. The coatings applied to crop seeds are a primary source of the contamination. The 2015 CFS report, Water Hazard—Aquatic Contamination by Neonicotinoid Insecticides in the United States, describes numerous exceedances of safe levels, including many findings exceeding EPA

<sup>&</sup>lt;sup>61</sup> *Id.*, pp. 9-10 (emphasis added).

<sup>&</sup>lt;sup>62</sup> See Petitioners' Interests in Appendix, Section II.

<sup>&</sup>lt;sup>63</sup> Morrissey, C.A., *et al.* 2015, *supra*, n.24, Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review.

benchmarks.<sup>64</sup> It documents contamination caused by coated seeds in a wide variety of rural habitats nationwide, typically via pathways that EPA failed to consider adequately when it approved the coating products.

Water concerns were clearly illuminated in late 2016 in another review paper by Sanchez-Bayo, *et al.*<sup>65</sup> The implications, partly attributable to coated seeds, are extremely alarming, summed in the Conclusion as:

Negative impacts of neonicotinoids in aquatic environments are a reality. Initial assessments that considered these insecticides harmless to aquatic organisms may have led to a relaxation of monitoring efforts, resulting in the worldwide contamination of many aquatic ecosystems with neonicotinoids.

The decline of many populations of invertebrates, due mostly to the widespread presence of waterborne residues and the extreme chronic toxicity of neonicotinoids, is affecting the structure and function of aquatic ecosystems. Consequently, vertebrates that depend on insects and other aquatic invertebrates as their sole or main food resource are being affected. Declines of insectivore bird species are quite evident so far, but many other terrestrial and amphibian species may be at risk.

Solutions must be found soon if we are to save the biodiversity not only of aquatic ecosystems, but all other ecosystems linked by the food web.

On January 12, 2017, EPA released its *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid.* While containing many conservative assumptions and admitted uncertainties, for seed treatment uses EPA found ongoing *chronic* effects for many aquatic invertebrates and some group likely to suffer *acute* effects. As discussed above, *supra* Section VI, while EPA failed to do the required ESA Section 7 analysis, it is transparent that

<sup>&</sup>lt;sup>64</sup> Carnemark, M., Jenkins, P., and Walker, L., *Water Hazard—Aquatic Contamination by Neonicotinoid Insecticides in the United States*, CFS, Washington, D.C., 2015, *at* www.centerforfoodsafety.org/files/neonic-water-report-final-242016 web 33288.pdf and Carnemark, M. *Water Hazard 2.0*, CFS, 2017.

<sup>&</sup>lt;sup>65</sup> Sánchez-Bayo F., Goka K., Hayasaka, D., *Contamination of the aquatic environment with neonicotinoids and its implication for ecosystems*, Front. Environ. Sci. 4:71 (2016) doi: 10.3389/fenvs.2016.00071, *at* http://journal.frontiersin.org/article/10.3389/fenvs.2016.00071/full (emphasis added).

<sup>&</sup>lt;sup>66</sup> EPA-HO-OPP-2008-0844-1086, at www.regulations.gov/document?D=EPA-HO-OPP-2008-0844-1086.

listed threatened and endangered aquatic invertebrates may be adversely affected by the same chronic and/or acute effects. Despite its own findings the agency has failed to take—or even propose—any solutions needed to alleviate these effects on those species or those essential aquatic ecosystems as urged by Sanchez-Bayo, *et al.*, *supra*.

#### IX. Labels on Neonicotinoid-Coated Seed Bags and Tags.

EPA requires labels to be placed onto the bags or other containers, or onto the affixed tags, of the unregistered pesticidal seeds, which include some sparse warnings superficially aimed at protecting pollinators and other environmental values.<sup>67</sup> While these amount to admissions of the seeds' pesticidal effects, the label language itself is unenforceable by EPA's own statements and its inactions.<sup>68</sup>

Even were it enforceable, the seed bag or tag language is utterly inadequate to reduce or mitigate the harm caused by contaminated neonicotinoid dust and talc, or the grown plants themselves, to honey bees—including those owned by the Beekeeper Petitioners. Further, the bag labels are inadequate to protect against the vast spectrum of other environmental and economic impacts, including, but not limited to, damage to soil health, harm to ESA-protected species and the extensive water contamination described above.

On the inadequacy of the labels, Petitioner Bret Adee (representing the nation's largest commercial beekeeping company) has stated:

...[a]s shown in our massive 2015 bee kill, the exemption of toxic dust coming off of the neonicotinoid-coated corn seeds means there are no legal consequences for the seed coaters or pesticide manufacturers whose chemicals killed our bees. Neither the state enforcement agents nor EPA's enforcement agents will take any action to stop or mitigate the harms. There are no enforceable labels on the seed bags that the farmer must follow to not cause

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<sup>&</sup>lt;sup>67</sup> See n.17, supra.

<sup>&</sup>lt;sup>68</sup> See EPA, Sulfoxaflor—Final Cancellation Order, dated Nov. 12, 2015, p.2, at https://www.epa.gov/sites/production/files/2015-11/documents/final\_cancellation\_order-sulfoxaflor.pdf.

dust-off that will kill honeybees. My direct experience is that whatever language EPA asks to be put on those seed bags is inadequate to protect bees. From my perspective, my right as a beekeeper to obtain pesticide law enforcement for such dust-off kills has become non-existent. That reduces not only my ability to protect my valuable livestock, but also my ability to make any civil or other claim that I might seek to bring against those in the chain of production and use of these pesticides.<sup>69</sup>

The seed coating companies that apply the liquid chemicals to the various crop seeds are not the applicators of the ultimate pesticidal products—the seeds. Rather, the crop farmers who plant the seeds are, including the Petitioner farmers herein. The farmers are the "users" who need—and in many cases, desire—clear label warnings and strong directions in order to protect their own surrounding environment. EPA misuses its labeling authority and arbitrarily assumes that the seed coating companies—applying the liquid coatings mostly in industrial buildings—can be given warnings and use directions adequate to ensure that FIFRA's safety standards will be met during the actual use of the pesticidal seeds in the environment.

### X. Past Statements by EPA, USDA Officials and Others.

Extensive statements by EPA and USDA officials, and in documents before the agencies, underscore their awareness of the harms of the coated seeds and the associated dust-off. Below is a non-exhaustive example of such statements:

# A) EPA's Pesticide Fact Sheet—Clothianidin:<sup>70</sup>

...assessments show that exposure to treated seeds through ingestion may result in chronic toxic risk to non-endangered and endangered small birds (e.g., songbirds) and acute/chronic toxicity risk to non-endangered and endangered mammals. Clothianidin has the potential for toxic chronic exposure to honey bees, as well as other nontarget pollinators, through the translocation of clothianidin residues in nectar and pollen ... [It] is

<sup>&</sup>lt;sup>69</sup> Decl. Adee p.2, *Anderson v. McCarthy*, No. 3:16-cv-00068-WHA, ECF No. 58 (N.D. Cal. Apr. 14, 2016).

<sup>&</sup>lt;sup>70</sup> EPA, Office of Prevention, Pesticides and Toxic Substances. Pesticide Fact Sheet—Clothianidin (May 30, 2003), *at* https://www3.epa.gov/pesticides/chem\_search/reg\_actions/registration/fs\_PC-044309\_30-May-03.pdf.

a systemic insecticide that is persistent and mobile, stable to hydrolysis, and has potential to leach to ground water, as well as runoff to surface waters.

# B) Report on the National Stakeholders Conference on Honey Bee Health:<sup>71</sup>

It is clear, however, that in some instances honey bee colonies can be severely harmed by exposure to high doses of insecticides when these compounds are used on crops, or via drift onto flowers in areas adjacent to crops that are attractive to bees. For example, dust produced in the process of planting pesticide-coated seeds has been shown to contain high levels of insecticide with the potential to harm bees.

# C) EPA's Team Preparing the 2013 Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents: <sup>72</sup>

Keen interest has been expressed by outside groups in contributing to the bee guidance, which has been under development since mid-2012, following a spring with an unusual number of bee mortality incidents either unexplained or which appeared to be associated with treated seed.

# D) Evidence EPA Collected from Non-Federal Experts in the Preparation of its 2013 Guidance:

For background on its Bee Incident Guidance, above, EPA convened a panel of experts, several of whom highlighted the role of neonicotinoid-coated seeds. Commercial beekeeper Randy Oliver identified: "dust from fields . . . dust from corn seeding . . . transport of systemic pesticides into crops or exposed weeds" as routes of pesticide exposure to his hives. Oliver also stated to EPA: "Exposure to planting dust kills the 'pollen hogs'—newly-emerged workers and drones that are feeding heavily on beebread. Next would be effects upon the nurse bees, who also consume the bulk of pollen in the hive." The most devastating effect of exposure by bees to neonicotinoid pesticides is a large number of dead bees appearing in front of and surrounding a hive. Other sub-lethal effects can be just as devastating, including "queen failure,

<sup>&</sup>lt;sup>71</sup> USDA, October 2012 Report on the National Stakeholders Conference on Honey Bee Health, p. 16, *at* http://www.usda.gov/documents/ReportHoneyBee Health.pdf.

<sup>&</sup>lt;sup>72</sup> EPA, undated memorandum (likely 2013). Draft Guidance for Investigation of Alleged Cases of Pesticide-Related Bee Mortality: Pros and Cons of Issues Surrounding Review and Release of the Guidance, *available at* perma.cc/P5VX-JS6T.

perma.cc/P5VX-JS6T.

<sup>73</sup> EPA, Undated survey responses. *Responses From Bee Experts* (collected in preparation for EPA's 2013 *Guidance for Inspecting Alleged Cases of Pesticide Related Bee Incidents*); Randy Oliver responses, pp. 1, 6.

[inability] to navigate correctly, inability to supersede during queen failure, sterile drones and/or inability to successfully copulate with virgin queens," and "loss of vigor by foragers, lack of veteran foragers that harvest proposes, [and] shortened lifespan of foragers." Dr. Eric Mussen of University of California, Davis, stated, "bees exposed to neonicotinoids looked 'anemic'; the bee colony is not necessarily killed; there seems to be 'downstream sickness' and the bees tend to be sluggish."

# E) EPA's Scientific Advisory Panel (SAP), Pollinator Risk Assessment Framework:

During that SAP in 2012, Purdue University Professor of Entomology Dr. Greg Hunt stated:

Well, I'll just speak to the seed treatment. Neonicotinoid seed treatments in particular, in the conceptual model, this is modeled—the EPA White Paper is only looking primarily at systemic movement plant parts. But clearly, we're seeing a problem with dust, particularly with corn planting and in regards to the soil. We see at least twice the concentrations of Clothianidin that we find in corn pollen. We're seeing a lot of reports, many of which apparently aren't getting transmitted to the EPA, and I think there is a lag in that also because, for example, in Indiana, the office of the state chemist has looked at 14 incident reports and they all came up positive for Clothianidin. In Ohio, there was something like 50 reports, incident reports, which again have not gotten their way to the EPA. In Ontario and Quebec, there are a lot of positive reports—over 130 of them, I understand—just from this year. <sup>76</sup>

#### **XI.** Other Systemic Seed Coating Chemicals.

The same factual concerns discussed above apply to other non-neonicotinoid, systemic seed coating products that EPA has already approved or has indicated its intent to approve, including, but not limited to, Fipronil, Sulfoxaflor, Cyantraniloprole and Flupyradifurone. Some of these may not yet be registered for seed coating use; however, based on EPA's practices with the neonicotinoids, it is foreseeable EPA will approve them for that use. If so approved they are likely to present the same class of harms to Petitioners as do neonicotinoid-coated seeds.

<sup>&</sup>lt;sup>74</sup> *Id.*, Randy Verhoek response, p. 5.

<sup>&</sup>lt;sup>75</sup> EPA, 2013. Meeting Minutes Teleconference: EPA and 'Bee Experts.' Tues. Feb. 26, Eric Mussen ("EMu") response, p. 2.

<sup>&</sup>lt;sup>76</sup> FIFRA Scientific Advisory Panel, 2012, Open meeting, Pollinator Risk Assessment Framework, Docket number: EPA-HQ-OPP-2012-0543 p.411, *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0039.

#### <u>ARGUMENT</u>

### I. EPA Has the Authority and Duty To Regulate Coated Seeds Under FIFRA.

Systemic neonicotinoid-coated seeds clearly fit within FIFRA's definition of "pesticide" because they are a "mixture of substances that are intended to prevent, destroy, repel or mitigate a pest," and would otherwise require registration prior to sale. 7 U.S.C. § 136(u)(1). Under FIFRA, EPA is charged with regulating pesticides, absent an exemption, including directing what data will support registration and evaluating whether a given pesticide meets FIFRA's safety standard. *Id.* § 136a. Specifically, EPA may not register a pesticide unless it determines that "it will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 36a(c)(5)(C), (D).

EPA is authorized under FIFRA to exempt certain pesticides from FIFRA's requirements. Namely, under 7 U.S.C. § 136w(b), the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." Given that EPA is not allowed to *register* a pesticide which will cause unreasonable adverse effects on the environment, it follows that EPA may not *exempt* pesticides that would cause unreasonable adverse effects on the environment. Put another way, EPA could not lawfully determine that a pesticide that causes "unreasonable adverse effects on the environment" is "of a character which is unnecessary to be subject to" FIFRA.

Pursuant to its authority under 7 U.S.C. § 136w(b)(2), EPA promulgated the Treated

Article Exemption, for "[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself." 40 C.F.R. §152.25(a). As currently written, the plain language of that exemption does not include systemic insecticide-coated seeds. Coated seeds do not fit within 40 C.F.R. §152.25(a) (which lacks any mention of "seeds"), because they are not intended "to protect the article or substance itself" as the regulation requires. First, the actual intent behind coating crop seeds with neonicotinoids and other systemic insecticides predominately is to protect the growing plant from pests that prey on living plant tissues, not to protect the seed "itself." As indicated, reviewing the fifteen coating product labels that EPA has registered since 2010 reveals that on thirteen of those labels the neonicotinoid ingredients are intended to protect the growing crop plants. 77 Only two of those labels explicitly claim protection of the planted seed itself by the neonicotinoid ingredient. Second, the coatings of these seeds do not remain on the seed, but instead "dust-off" into the air during planting, or slough off into the soil. The fact that 80% to 90% of the coating chemicals move off the seed and plant into the surrounding air, soil, marginal vegetation and waters, illustrates that the bulk of the treatment does not remain in or on the "treated article." Because the Treated Article Exemption requires that the treatment be for the protection of the article itself, it should be a necessary condition that the treatment largely remains on the treated article.

However, EPA's current interpretation of the Treated Article Exemption includes systemic coated seeds under this exemption, despite the intended and actual pesticidal effects beyond the articles (seeds) themselves.<sup>78</sup> While the Agency has not made this interpretation clear in any regulation or formal interpretation, EPA's practice of neither requiring registration of the seeds nor imposing enforceable labeling on their bags or tags speaks clearly. EPA can and must

<sup>&</sup>lt;sup>77</sup> See n.17, supra.

<sup>&</sup>lt;sup>78</sup> EPA, 2013 *Guidance for Inspecting Alleged Cases of Pesticide Related Bee Incidents*, p. 7, at https://www.epa.gov/sites/production/files/2013-09/documents/bee-inspection-guide.pdf.

correct this interpretation and practice of exempting coated seeds from registration and labeling by clarifying that the Treated Article Exemption does not include systemic coated seeds.

Not only does the extension of the Treated Article Exemption to these pesticidal seeds violate its plain language, it violates the basic FIFRA safety standard. EPA cannot exempt a pesticide that violates this safety standard, i.e., that the pesticides as commonly used will not cause unreasonable adverse effects to the environment. 7 U.S.C. § 136a(c)(5). As shown above, these seeds do cause unreasonable adverse effects to the environment, including to the pollinators that support U.S. agriculture and make up the livelihoods of the Beekeeper Petitioners. EPA has failed to fully evaluate the harms from coated seeds in its approvals of the liquid coating products alone. EPA's own pollinator RAs for imidacloprid, clothianidin, and thiamethoxam do not fully examine their risks when used as seed treatments, due to EPA's exemption for the seeds. Most explicitly, the RAs exclude any risk assessment or mitigation for the abraded seed coatings and the associated "dust-off," despite EPA's awareness that these insecticides are spread far from where the exempted seeds were planted.<sup>79</sup> Even though agency officials are aware of harm occurring as a result of these seeds, their exemption blinds them to the full magnitude of the damage. Many incidents of damage from coated seeds simply go uninvestigated. Even reports of massive honey bee colony kills due to coated seeds may never lead to enforcement because they are not caused by registered "pesticides" covered under FIFRA. Petitioner beekeepers have no incentive to report such kills to the agency due to its well-known lack of enforcement.

By approving only the liquid coating products applied to the seeds indoors, EPA allows manufacturers of systemic seeds of the various crops (>24) to avoid a comprehensive EPA

<sup>&</sup>lt;sup>79</sup> EPA's Preliminary Pollinator/Bee Risk Assessments for Imidacloprid, Clothianidin and Thiamethoxam cited in n.29 and n.30, *supra*.

determination of whether those particular crop seeds and their associated dust-off, soil and water contamination and other externalized effects constitute "unreasonable adverse effects on the environment" as required under 7 U.S.C § 136a(c) (5). Further, EPA's exemption allows manufacturers of the various pesticidal seeds to evade the two classes of EPA notices that must go in the Federal Register under FIFRA and EPA's regulations. 7 U.S.C. § 136a(c)(4); 40 C.F.R. § 152.102. This evasion denies Petitioners and the public essential notice by which they could be allowed to comment to EPA on proposed registrations. The lack of the required published notices also denies Petitioner beekeepers the information needed to protect their bees from fields planted with the numerous exempted crop seeds.

If EPA had followed the FIFRA-mandated registration process for the pesticidal seeds at issue, many of them likely would not have been registered, not been heavily advertised and sold, and they would not have inflicted the damages the Petitioners that they now inflict. Other regulators (in Europe and on our own U.S. wildlife refuges) are taking action to restrict or stop the use of these dangerous pesticides. EPA cannot continue to exempt them from FIFRA. Without the requested action, EPA will allow the continued destruction of the nation's commercial and wild pollinators, damage to agricultural soils, and harm to non-target wildlife including ESA-protected species, to the severe detriment of U.S. agriculture and contrary to EPA's duty to regulate pesticides to protect the public and the environment.

#### II. EPA's Exemption of Coated Seeds Is Unlawful.

EPA does not have the authority to continue its wholesale exemption of coated seeds from FIFRA's requirements, because FIFRA does not authorize exemptions of pesticides that require regulation, especially not those pesticides that cause unreasonable adverse effects to the environment. Accordingly, EPA's current interpretation of the Treated Article Exemption and

<sup>&</sup>lt;sup>80</sup> See EU and U.S. National Wildlife Refuge System measures cited in n.33 and n.36, supra.

practice of exempting coated seeds from registration and labeling is *ultra vires*. 5 U.S.C. § 706(2)(C).

EPA's exemption of coated seeds is also arbitrary and capricious under the APA. *Id.* § 706(2)(A). First, EPA's actions are arbitrary and capricious because they are counter to the available evidence that coated seeds cause significant adverse effects on the environment. *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983). Second, EPA's interpretation of the Treated Article Exemption as to coated seeds is inconsistent with its other interpretations in comparable situations where the agency found a treated article not to be exempted due to adverse pesticidal effects beyond the article itself, including its non-exemption of anti-fouling boat paint and other articles. §1

Finally, EPA's exemption of these coated seeds violates its duty under ESA to ensure that its actions do not jeopardize the continued existence of any protected species. 16 U.S.C. § 1536(a). As shown above, among the impacts from these pesticidal seeds are harms to threatened and endangered species, including invertebrates and birds. Despite the fact that the pesticidal seeds unregulated by EPA "may affect" many protected species either directly or indirectly, EPA has never consulted with the expert Services to determine whether its exemption of coated seeds is likely to jeopardize these species. Moreover, this assessment is missing from EPA's registration of the liquid coating products and active ingredients. As noted above, even if EPA were to consult under the ESA on these products, to date the agency has ignored the full effects of the use of the coated seeds in the field due to its exemption.

Because EPA's ongoing exemption of coated seeds violates FIFRA and the APA and poses adverse effects to a large number of threatened and endangered species protected under the

<sup>&</sup>lt;sup>81</sup> See sample boat hull paint label for *Pro-Line 1080 H Hard Vinyl Anti-Fouling Paint*, EPA registration number 577-549, *at* https://www3.epa.gov/pesticides/chem\_search/ppls/000577-00549-20031002.pdf.

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ESA, EPA must take the requested actions.

**CONCLUSION** 

For the reasons stated herein Petitioners request that EPA either amend or formally re-

interpret the Treated Article Exemption, 40 C.F.R. §152.25(a), to clearly communicate to the

regulated community that systemic pesticidal seeds intended to kill pests of the plants are not

included under the Treated Article Exemption and are therefore subject to FIFRA's requirements

for registration and labeling. Petitioners also request EPA to aggressively enforce FIFRA's

registration and labeling requirements for each separate seed product coated in systemic

insecticides, in order to properly discharge its duty to protect the public and environment.

DATED this 26th day of April, 2017.

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#### <u>APPENDIX</u>

#### PETITIONERS' INTERESTS

The eleven Petitioners are nationally-representative beekeepers, farmers, and public interest organizations harmed by EPA's actions and inactions described, *supra*.

#### **Beekeeper Petitioners**

Petitioner Bret Adee is a resident of Bruce, South Dakota. He is a third-generation commercial beekeeper and a co-owner of Adee Honey Farms. Founded in 1957, Adee Honey Farms is the nation's largest beekeeping operation. It manages some 90,000 honey bee colonies and has about fifty full-time employees. Its operations have been harmed over several years by the neonicotinoid seed coatings. The colonies, in many cases, cannot be placed so that the free-ranging bees will be able to avoid contaminated crops, dust, soil, marginal vegetation, and water that results from the seed coatings, which are overused. Adee Honey Farms has experienced abnormally high incidences of hive failure in recent years. Prior to 2005, they would expect to lose between three to eight percent of their colonies over the winter. Now, they consider it a good year if they lose only twenty percent. In 2012, for example, they lost forty-two percent of their hives over winter, but by the time they came around to pollinate almonds in the early spring, their losses were at fifty-five percent. For the summer of 2015, the Adees had a massive exposure to clothianidin dust-off that resulted in an estimated 10,000 severely weakened honey bee colonies. The results to the company include lost income, increased expenses and work overload, and emotional distress from seeing their animals killed or weakened. Mr. Adee and his family fear for the future of their business—and commercial beekeeping in general—if the current overuse of neonicotinoids and other pesticides continues. Mr. Adee is the President of the Pollinator Stewardship Council and co-Chair of the National Honey Bee Advisory Board. He also is a member of the American Honey Producers Association, the South Dakota Beekeepers Association, and the California State Beekeepers Association.

Petitioner American Beekeeping Federation (ABF) is a 501(c)(5) organization founded in 1943, headquartered in Atlanta, Georgia. ABF is dedicated to advancing the interests of all beekeepers, large or small, and other interests associated with the industry to ensure the future of the honey bee. ABF currently has approximately 1,500 members, making it the largest beekeeping organization in the United States. Approximately twenty-five percent of the commercial beekeepers in the United States are members of ABF. ABF members harvest roughly thirty percent of the honey produced in the United States each year, a lot of that from smaller producers.

Petitioner American Honey Producers Association (AHPA) is a non-profit agricultural association incorporated in Oklahoma in 1969. The organization is dedicated to promoting the common interest and general welfare of the American honey producer. AHPA currently has about 400 members who make their living from the production of honey. Collectively, AHPA members produce as much as fifty percent of the United States' honey.

Petitioner Jeff Anderson has been the owner of California Minnesota Honey Farms for nineteen years. It is a migratory beekeeping operation based in Eagle Bend, Minnesota; and Oakdale, California. In addition to Mr. Anderson, the business employs one full-time employee, as well as three seasonal employees. He has been a commercial beekeeper since 1976. Mr. Anderson is a member of the Minnesota Honey Producers Association, the California State Beekeepers Association, the American Honey Producers Association, the National Honey Bee Advisory Board, and the Pollinator Stewardship Council. Since about 2004-05, his percentage of hives lost each year has increased dramatically. In 2012, for example, he had 3,150 hives in April, but by February 2013, he was down to just 998 hives, meaning he lost almost 70% of hives that year. Not only is Mr. Anderson losing hives at rates that are unprecedented, but remaining hives are far less robust. It is plain from recent years that he is getting significant summer mortality—a time when bee populations should be healthy due to warm weather, long days, and food abundance—from the dominant Minnesota crops: corn and soybeans. It is virtually impossible for honey bees to avoid these crops in central Minnesota; nearly all of them are seed-treated with a combination of two neonicotinoid pesticides, clothianidin and thiamethoxam. There are other consequences of this hive health pattern which adversely affect his business and livelihood. First, sick or poorly-populated hives cannot produce much honey. This is apparent when observing his annual honey production records. Prior to 2005, he would expect to harvest an average eighty pounds of honey per live hive annually. In recent seasons, Mr. Anderson's hives have averaged only about forty pounds of honey. His income has drastically suffered as a result and his expenses to keep his remaining hives alive have dramatically increased. The workload and personal stress are intense. His experience and observations are that the exempted neonicotinoid seed coatings, toxic dust, and other contamination from them have played a major role. Test results for some incidents confirm this.

Petitioner David Hackenberg is a commercial beekeeper residing in Lewisburg, Pennsylvania. He has been keeping bees for fifty-four years, through his family business Hackenberg Apiaries. His experience includes serving twelve years on the National Honey Board, has served as President of the American Beekeeping Federation, and as Chair and co-Chair of the National Honey Bee Advisory Board. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation. In 2006, he saw huge losses and was the first beekeeper known to suffer what was described by scientists as Colony Collapse Disorder. These disappearances coincided with the exempted neonicotinoid pesticidal seeds coming on the market in large numbers. This damage at least partly resulted from the use of neonicotinoid seed coatings in row crops nationwide. This is compounded by the lack of labels on the seed bags adequate to inform the crop farmers how to avoid harm to bees, and the lack of any enforcement when bees are harmed by these seed coating. Mr. Hackenberg has about 2,000 hives now. His annual losses have run seventy-five to eighty percent or with continual protein feeding, they can be held closer to sixty percent losses, but both these levels are excessive. The economic damage to his business, increased expenses and work demand, and personal stress from seeing huge numbers of his bees die have all directly harmed him. His experience and direct observations are that the seed coatings, dust, and other contamination from them have played a major role.

Petitioner **Pollinator Stewardship Council (PSC)** is a nonprofit organization incorporated in Kansas in 2012. The mission of PSC is to defend managed and native pollinators

vital to a sustainable and affordable food supply from the adverse impacts of pesticides. As pollination is required for one-third of the nation's food supply, PSC accomplishes it mission by: (1) ensuring that state agencies and EPA enforce laws to protect pollinators from pesticides; (2) providing advocacy, guidance, and tools for beekeepers to defend their bees from the detrimental effects of pesticides; and (3) raising awareness about the adverse impacts of pesticides on pollinators. PSC has previously stated its position in opposition to the "treated article" exemption being applied to neonicotinoid-coated seeds because it leads to excessive and unnecessary use of these insecticides. Beekeepers that PSC represents typically cannot escape many harmful effects of this overuse, nor will EPA or the state agencies enforce against misapplication of the exempted seed coatings, even when major bee kills result. Additionally, the losses inflicted on native pollinators, which lack any management, in many cases may be more severe than the damage to managed pollinators. On the whole, the damages resulting from the exemption EPA has given to the pesticidal coated seeds are unacceptable to PSC.

#### **Farmer Petitioners**

Petitioner Lucas Criswell resides near Lewisburg, in central Pennsylvania. He farms about 1,800 acres total of mostly corn, soybeans, and small grains. He has been doing this for twenty years, and is familiar with the seed choices for these crops and the effects of using different seeds as well as the effects of neonicotinoid coatings. He is very concerned about the non-availability of uncoated corn seeds of the high-quality hybrid varieties. He also is concerned because he has seen that the exempted neonicotinoid-coated seeds are used as a form of "insurance," when in most situations farmers do not need coated seeds. As a result of their overuse, he has observed harm to beneficial insects and the overall health of the soil. In the case of soybeans, Mr. Criswell planted coated seeds for several years and then quit. Unlike corn, there are many good uncoated soybean varieties available from seed dealers. When he switched, he saw no decrease in overall average yields or profitability from his soybean acreage. He switched because it was clear that the coated seeds he used in the past were causing an increase in slugs in the fields, a harmful and hard-to-control crop pest. There were slug outbreaks because the neonicotinoid killed beetles that kept the slugs under control. Mr. Criswell also quit because he was concerned the unnecessary overuse of the chemicals violated Integrated Pest Management, an important principle for his farming. He switched away from neonicotinoid-coated corn seeds more recently, but it is challenging due to their near complete domination of the available corn seed market. Mr. Criswell is concerned that too many farmers, including him at times, have been using them unnecessarily and paying unnecessary costs for the pesticidal coating. He is concerned that the overall effect harms the soil and farmers themselves in the long run.

Petitioner **Gail Fuller** is a farmer residing near Emporia, Kansas. He farms about 1,000 acres of mixed grains, including sorghum, corn, barley, soybeans, and wheat. He regularly used neonicotinoid-coated seeds in the past on some of his crops. He has switched to non-coated seeds for all the crops where it was feasible based on seed availability. Mr. Fuller is an active proponent for soil health and he has noticed that the neonicotinoids can damage soil health and beneficial insects. He is concerned that he used these chemicals unnecessarily as that is not consistent with good soil health or good farming. He is concerned about how the exempted neonicotinoids appear to put monarch butterflies, honey bees, and other beneficial insects at risk.

Since cutting back on coated seeds, he has observed more biologically diverse and sustainable ecosystems on and around his farmland, without reducing his typical yields.

### **Public Interest Organization Petitioners**

Petitioner American Bird Conservancy (ABC) is a national, nonprofit membership organization, headquartered in The Plains, Virginia, dedicated to conserving native birds and their habitat throughout the Americas. With more than 10,000 members nationwide, ABC works to innovate and build on sound science to halt extinctions, protect habitats, eliminate threats, and build capacity for bird conservation. ABC has had a long-standing program to address the significant threat that pesticides pose to birds. It works to cancel or restrict the registrations of the most dangerous products, to improve the evaluation and monitoring of pesticides and their effects on birds, to spearhead scientific research, and to engage the public in protecting birds and other wildlife. The 2013 ABC report, The Impact of the Nation's Most Widely Used Insecticides on Birds, concluded that neonicotinoid-coated seeds are lethal to birds and to the aquatic biological diversity upon which they depend. The nation's birds, and ABC's members, are directly and indirectly harmed by the neonicotinoid seed coating chemicals that are blanketing croplands, contaminating watersheds, and poisoning birds, bees, butterflies, and other organisms. ABC has advocated for more than three years to EPA and other federal agencies to curb the overuse of coated seeds. ABC also has urged the Agency to eliminate the coated seeds' exemption from registration as pesticides under FIFRA.

Petitioner Center for Food Safety (CFS) is a Washington, D.C.-based, public interest, nonprofit membership organization with offices in San Francisco, CA; Portland, OR; Honolulu, HI; and Washington, D.C. CFS's mission is to empower people, support farmers and protect the earth from the harmful impacts of industrial agriculture. Through legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has more than 830,000 consumer and farmer supporters across the country. It seeks to protect human health and the environment by advocating for thorough, science-based safety testing of new agricultural products prior to any marketing and cultivation of crops in a manner that minimizes negative impacts such as increased use of pesticides and evolution of resistant pests and weeds. A foundational part of CFS's mission is to further the public's and its members' fundamental right to know what is in their food and food production methods and technologies.

Petitioner **Pesticide Action Network of North America (PANNA)** is an Oakland, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. For nearly thirty years, PANNA has worked to replace the use of hazardous pesticides with healthier, ecologically sound pest management across the United States and around the world. PANNA provides scientific expertise, public education and access to pesticide data and analysis, and policy development and coalition support to more than 100 affiliated organizations in North America. PANNA has more than 125,000 members across the United States. PANNA's members live, work, farm, and recreate in areas of the country where pesticides such as the neonicotinoid insecticides are applied, and in which the pesticides and contaminated dust drift and transport occurs, and thus have a strong interest in ensuring that EPA protect public health and the environment from this contamination. PANNA's members are highly concerned by the

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effects of the unregulated neonicotinoid-coated seeds on honey bees, bumble bees, butterflies, beneficial invertebrates, wild pollinators, water, aquatic invertebrates, food chains, ecosystem sustainability generally, and ultimately on humans via food and water consumption. The lack of enforceable labeling on these pesticidal seeds, and their prophylactic overuse, violate bedrock principles PANNA seeks to protect as far as only using pesticides as a last resort, and then only when they have strong and clear warnings and enforceable use directions. PANNA has urged EPA to eliminate the coated seeds' exemption from registration as pesticides. PANNA has also urged EPA (as well as the United States Department of Agriculture and Department of Justice) to address issues around the lack of fairness, transparency, and farmer choice in the seed marketplace.

JS-CAND 44 (Rev. 10/2020)

# 2 Filed 12/14/21 Page 1 of 2 R SHEET Case 3:21-cv-09640

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

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CENTER FOR FOOD SAFETY and PESTICIDE ACTION NETWORK NORTH AMERICA

- (b) County of Residence of First Listed Plaintiff San Francisco (EXCEPT IN U.S. PLAINTIFF CASES)
- (c) Attorneys (Firm Name, Address, and Telephone Number)

#### **DEFENDANTS**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 3016 MICHAEL REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

1			One Box Only)					"X" in One Box for Plaintiff	
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**DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)** 

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JUDGE

SAN JOSE

DOCKET NUMBER

**EUREKA-MCKINLEYVILLE** 

DATE 12/14/2021

VIII. RELATED CASE(S),

IF ANY (See instructions):

SIGNATURE OF ATTORNEY OF RECORD

/s/ Sylvia Shih-Yau Wu

#### INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-CAND 44

Authority For Civil Cover Sheet. The JS-CAND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I. a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
  - b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
  - Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)."
- Jurisdiction. The basis of jurisdiction is set forth under Federal Rule of Civil Procedure 8(a), which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
  - (1) United States plaintiff, Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.
  - (2) United States defendant. When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
  - (3) Federal question. This refers to suits under 28 USC § 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
  - (4) Diversity of citizenship. This refers to suits under 28 USC § 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity
- III. Residence (citizenship) of Principal Parties. This section of the JS-CAND 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- Origin. Place an "X" in one of the six boxes.
  - (1) Original Proceedings. Cases originating in the United States district courts.
  - (2) Removed from State Court. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.
  - Remanded from Appellate Court. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing (3)
  - (4) Reinstated or Reopened. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
  - (5) Transferred from Another District. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
  - Multidistrict Litigation Transfer. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.
  - (8) Multidistrict Litigation Direct File. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

Please note that there is no Origin Code 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC § 553. Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Federal Rule of Civil Procedure 23.

Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

- VIII. Related Cases. This section of the JS-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- Divisional Assignment. If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated."

Date and Attorney Signature. Date and sign the civil cover sheet.